臺灣介入性心臟血管醫學會

63 期

TAIWAN SOCIETY OF CARDIOVASCULAR INTERVENTIONS

107.5.5『Meet the Masters』
107.6.9『Carotid Stenting Training Course』
107.6.23『Transcatheter Closure of ASD and PFO』
學會活動預告：
107.8.19『介入藥物研討會』
107.9.15-16『秋季會』

臺灣介入性心臟血管醫學會會訊 (第六十三期, Jun., 2018)

發行人 Publisher	殷偉賢 Wei-Hsian Yin
主編 Editor-in-Chief	盧澤民 Tse-Min Lu
副主編 Deputy Editor-in-Chief	陳盈憲 Ying-Hsien Chen
執行編輯 Executive Editor	林重佑 Chung-Yu Lin
	陳翰興 Han-Hsing Chen
	劉彥廷 Yan-Ting Liu
	潘建廷 Chien-Ting Pan
	蕭文彬 Wen-Pin Hsiao
	蔡承烜 Cheng-Hsuan Tsai
	彭瑋婷 Wei-Ting Peng

地址：10041 台北市中正區忠孝西路一段 50 號 16 樓之 18

Address: 16F-18, No.50, Sec. 1, Zhongxiao W. Rd., Taipei 10041, Taiwan, R.O.C.

TEL:+886-2-2381-1698 FAX:+886-2-2381-5198

E-mail:tsci.med@msa.hinet.net website:http://www.tscimd.org.tw

目錄

各位會員大家好

四月下旬，一個嶄新的會議形式在北京阜外醫院正式上路。在 4 月 23 日至 29 日的一周時間內，通過網路直播、線上 / 線下互動的會議形式，在前 5 天時間內共計進行了 130 例 CTO 手術演示，後兩天則安排了多場學術講座。這次會議設立 4 大手術演播室（如同四家電視頻道）輪流直播各大中心 CTO 手術，同時邀請國內外 CTO 專家講評討論，全程與術者互動，交流切磋心得。醫生可以通過多種網路方式登錄觀看直播，包括微信直播小程式、微信網頁直播、電腦網頁版、APP 程式等。一週下來，網路觀眾的總流覽量超過 12 萬人次。事後的大資料分析顯示，CTO WEEK 活動結束之後的一個月，視頻重播觀看人數仍在持續增長，充分顯現這次會議引發的正向學習效應及深遠影響。

這場 CTO 手術直播盛會共有來自世界各地共 13 家醫學中心的 142 位專家參與，其中大陸地區專家 117 位，香港和澳門專家各 2 位，臺灣專家 8 位，歐美和日本專家 7 位，其他國家專家 6 位。

臺北振興醫院這次也在學會的大力支持下參會，包括盧澤民秘書長、曹殿萍主任、顧博明主任、任勗龍醫師及蔡政廷醫師等人輪番上陣手術，吳炯仁前理事長則在大陸參加手術。

針對這次會議，個人有幾點感想：

第一、近年來導管器械和治療技術與觀念的日新月異、數點陣圖技術的突飛猛進，加上無遠弗屆的網路傳播，CTO 已經由過去少數所謂「大師」的「絕學」，逐漸普及為一般介入醫師也可以經由固定學習路徑而逐步上手的技術。本次 CTO WEEK 會議期間，歐美、日本、臺灣及中國策略同台登場比對，各種分岐的治療路徑有漸漸匯流的趨勢。對於 CTO 的處置，大家有了相當程度的共識，雖然各別術者間針對不同的解剖形態仍存在一些差異。也就是說，這次會議展現了當下最新最真實的 CTO 技術水準，也展示了 CTO 技術的快速進步，手術成功率越來越高，併發症越來越少。我們在攻克這個冠脈介入最困難堡壘的戰鬥上，已經取得重大戰果，這對有治療需求的許多病人而言，實為一大福音！

第二、如同大會主席吳永健教授所言：CTO WEEK 創新會議形式，乃是未來「行之大勢，業之所趨」。將來對介入學界，甚至於整個心臟學界都會產生重大影響。這次會議從活動組織、病例手術、媒體轉播等多方面，借助網路進行傳播及大資料收集，同時兼具了「服務」、「教學」與「研究」：服務了病患、教育了醫師、開創了新的研究方式，也為這樣的會議形式奠定了學術基礎。一如所有醫療科技的發展，CTO 技術的進步建立在臨床需求的基礎上。病人期待安全、有效的導管技術解決 CTO 問題，催迫醫師必須回應並提供這項服務。這次嶄新的會議形式，更加開放的吸引了更多專家積極參與，以不同的風格、不同的術式、不同的理念，通過立即互動的方式激發醫師們的學習熱情，同時推動了醫學傳播教育方式的創新。再試想一下，要做一個 13 個中心，收案 130 例的 CTO 研究需要耗時多久，花費多少人力？但這次會議結束後不到兩個月，相關的結果已經出爐。這是何等有效率的資料收集方式。

理事長的話

第三、根據初步資料顯示：在這 130 例 CTO 病例中，平均年齡 57.1 歲，73 例右冠狀動脈 CTO，48 例前降支 CTO，9 例迴旋支 CTO，J-CTO 評分平均 2.61，SYNTAX 評分平均 28.2，1/3 的患者是先前嘗試開通失敗的案例。手術有 74 例採用正向技術，56 例採用逆向技術，手術總成功率達到 88.5%；其中正向技術的成功率高達 94.6%，逆向技術的成功率為 80.4%。至於技術參數，導絲通過 CTO 平均耗時 37.7 分鐘，逆向技術的通過時間稍長；平均 X 線透視 54.1 分鐘，X 線透視劑量 4361 mGy，顯影劑中位使用量為 277 ml。在所有這些 CTO 手術中，只有逆向技術組發生了 2 例大出血，沒有死亡、心包填塞、圍術期心肌梗塞或緊急再介入等嚴重併發症發生，住院期間僅發生 3 例不良事件。這些資料說明，當前兩岸 CTO 術者的技術已經追日超歐趕美，達到非常高的水準。

第四、個人覺得最值得我們注意及深思的是這次會議大陸年輕 CTO 術者表現出色，甚至獨當一面。近兩三年，個人參加許多會議，認識不少大陸中生代，甚至新生代的介入醫師。直覺的印象是大批年輕醫生在介入的舞臺快速成長，有所成就。而「老中青」三代延續技術而又各展風采，老的願教、中青代願學，因此造成 CTO 技術的快速進步及普及。當下，更多年輕醫生加入冠脈介入的行列，積極行動冀能攻克 CTO，而網路的普及剛好扮演了推波助瀾的重要角色，提供了一個為臨床醫生學習交流、切磋技藝的平台，相信將來會有更多的教育活動應運而生。個人加入了許多微信學習群組，幾乎無時無刻沒有病例、教育訊息、會議網路直播、及討論訊息。由於每日進來的訊息太多，只好關靜音，在閒時才能挑重點看看，這也反映了大陸現階段求知若渴的現況，這樣積極的學習熱忱是非常值得我們欽佩的！

因此，個人深切感受到我們學會在承先啟後過程中的重責大任。未來兩年，我們將會透過推動一系列的活動，包括「Meet the Masters」（限制四十歲以下會員投稿）；擴大舉辦 TSCI Live Courses ，今年會有 Rota/bifurcation Course 、Peripheral Course 、CTO Course 等等，提供更多平台讓「老中青」能有更多交流，中青輩藉由網路平臺，有更多嶄露頭角的機會！希望臺灣在下一波的介入浪潮中能取得領先的優勢。最近接觸到許多前輩先進，我感到大家都有非常強烈的「傳承」使命感。雖然臺灣介入的土壤受主客觀環境的限制，不一定那麼肥沃，但相信集合學會菁英群策群力，仍然可以培育出更優秀的下一代人才，在世界舞臺上發光。

總之，時代潮流的已經將介入治療推入第五個十年。追求更加微創、安全、有效的精準醫療不但是病人端，也應該是醫界未來持續努力的方向。不只如此，我們還要準備好迎接鋪天蓋地而來的網路形態教育和會議趨勢。最後別忘了！「Cardiologists never die」！我們更要有終身學習的觀念和實踐，尊敬並熱愛我們的專業。

理事長 殷偉賢

2018.06

臺灣介入性心臟血管醫學會 入會申請書

填表日期： 年 月 日

姓　　名		性　別	□男　□女	貼相片處 (實貼一張)
英文姓名		身分證 號　碼		
出生日期	年　　月　　日	出生地	省(市) 縣(市)	
最高學歷	學校　　科系（所）			
現任醫院		單位/職務	/	
戶籍地址		電話(必填)	O:	
通訊地址	□同戶籍地址 □通訊地址 _____		H: M:1. 2.	
E-mail(必填)	@		Fax:	
最近一年介入性工作經歷	(1) 醫院：_____ 期間： ___ 年 ___ 月至 ___ 年 ___ 月 醫師主管姓名：_____ 列印後主管簽名：_____ (2) 醫院：_____ 期間： ___ 年 ___ 月至 ___ 年 ___ 月 醫師主管姓名：_____ 列印後主管簽名：_____ (3) 醫院：_____ 期間： ___ 年 ___ 月至 ___ 年 ___ 月 醫師主管姓名：_____ 列印後主管簽名：_____			
推薦會員（1）	姓　　名：_____ 列印後簽名：_____	推薦會員（2）	姓　　名：_____ 列印後簽名：_____	

審查結果 (此欄由審查人員填寫)	□ 同意入會 □ 不同意入會 審查人員：	會員類別	□ 普通會員 □ 準會員 □ 名譽會員 □ 贊助會員	會員證號　碼	

會務活動 - 入會申請書

本人茲遵照　貴會章程之規定，申請加入　貴會為會員，遵守 貴會一切章程、簡則、決議等，謹此檢具各項證件，敬希　鑒核准予入會。

此致　臺灣介入性心臟血管醫學會

申請人：　　（簽章）

中　華　民　國　　年　　月　　日

繳驗資料：

□1. 入會申請表一份（共兩面）
□2. 本人二吋照片共三張
□3. 身分證正反面影本一份
□4. 最高學歷畢業證書影本一份
□5. 醫師會員－心臟專科醫師證書影本一份（若無，請附醫師證書影本一份）
　　醫事會員－師級醫事人員資格證書（護理師或放射師或醫檢師）影本一份
□6. 服務（在職）證明正本一份

注意事項

一、準會員申覆為普通會員：

1. 請在入會申請書左上角自行加註 ”準會員申覆普通會員” 字樣。
2. 證明從事介入性心臟血管醫學實務工作滿一年，須由現職主管簽章。

二、列印入會申請表格，填寫完整後，將紙本資料備齊全，郵寄至學會進行甄審。

三、介入性工作經歷

1. 醫師準會員真正從事介入性工作日起算，醫師普通會員指取得心臟專科證書起算。
2. 醫事人員指真正從事介入相關工作日起算。

四、醫師申請入會之兩位推薦會員，必須為本會之**普通會員**。

五、介入性工作經歷須由**現職之醫師主管在「最近一年介入性工作經歷」欄位親自簽名**。

臺灣介入性心臟血管醫學會 秘書處
地址：10041 台北市中正區忠孝西路一段 50 號 16 樓之 18
TEL：02-23813098
FAX：02-23815198
E-mail：tsci1.med@msa.hinet.net

介入藥物研討會

2018 Aug. 19 (Sun.)

財團法人張榮發基金會801會議室
（台北市中山南路11號）

09:00
16:30

TSCI臺灣介入性心臟血管醫學會
Taiwan Society of Cardiovascular Interventions

臺灣介入性心臟血管醫學會
Taiwan Society of Cardiovascular Interventions

介入藥物研討會

日期：107 年 8 月 19 日(週日) 09:00-16:30

地點：財團法人張榮發基金會 801 會議室(台北市中山南路 11 號)

時間	講題	講師	座長
09:00	**OPENING**	殷偉賢理事長	
Debate 1: What Should Be the Preferred Long-term Oral $P2Y_{12}$ Inhibitor in ACS Patients Undergoing PCI ?			
09:05	Brilinta	劉秉彥	常敏之
09:20	Plavix	郭風裕	
09:35	Efient	林彥宏	
09:50	Rebuttal (3 min each)		
10:00	VOTE		
10:05	**Special Lecture:** Should Antithrombotic Treatment Strategies in East Asians Differ from Caucasians?	Young-Hoon Jeong	李文領
10:35	Q & A		
10:40	Coffee Break		
Debate 2: What Should Be the Preferred Anti-diabetic Drugs beyond Metformin in Type 2 Diabetic Patients Undergoing PCI ?			
10:55	GLP1-RA	吳造中	方慶章
11:07	SGLT2i	林志弘	
11:19	Rebuttal (3 min each)		
11:25	VOTE		
11:30	**Lecture:** Hot Topic in Thrombosis Management: Cancer-associated Thrombosis (CAT)	林宗憲	邱俊仁
11:50	**Lecture:** How to Manage HFrEF in Patients Undergoing PCI ?	王宗道	盧澤民
12:10	Lunch		

臺灣介入性心臟血管醫學會
Taiwan Society of Cardiovascular Interventions

介入藥物研討會

時間	講題	講師	座長
Debate 3: What Should Be the Preferred Anticoagulant in Asian Patients with Non-valvular AF and Stable CAD in 2018?			
13:00	Edoxaban	邱昱偉	洪大川
13:12	Apixaban	李應湘	
13:24	Rivaroxaban	詹益欣	黃偉春
13:36	Dabigatran	黃柏勳	
13:48	Rebuttal (3 min each)		
14:00	VOTE		
Debate 4: Which Evidence-based DOAC Should Be the Preferred Dual Anti-thrombotic Regimen in Non-valvular AF Patients Undergoing Elective PCI with BMS or DES ?			
14:05	P2Y12 Inhibitor with Rivaroxaban?	王宇澄	曹殿萍
14:17	P2Y12 Inhibitor with Dabigatran?	黃建龍	
14:29	Rebuttal (3 min each)		
14:35	VOTE		
14:40	Coffee Break		
Debates 5: Which Should Be the Preferred Management Regarding Lipid-lowering Therapy in Statin-intolerant Patients Undergoing Elective PCI ?			
14:55	Oral Non-statin Medications	朱志生	王光德
15:07	PCSK9 Monoclonal Antibodies	洪惠風	
15:19	Rebuttal (3 min each)		
15:25	VOTE		
15:30	**Lecture:** Evaluation of Long-term Cardiovascular Outcomes after Acute Coronary Syndrome during Treatment with PCSK9 Monoclonal Antibodies: What We Learn from the ODYSSEY OUTCOMES Trial	趙庭興	鄭書孟
15:55	**Lecture:** PCSK9 Inhibition and Cardiovascular Risk: Insights from the FOURIER Trial	吳卓鍇	王怡智
16:20	**TAKE HOME MESSAGE**	謝宜璋 主委	

AUTUMN SCIENTIFIC MEETING • PERIPHERAL COURSE

2018 TSCI
秋季會 暨
週邊介入手術示範課程

09.15 — 16

高雄義大皇家酒店

高雄市大樹區學城路一段153號

TSCI 臺灣介入性心臟血管醫學會

TAIWAN TRANSCATHETER THERAPEUTICS

LIVE COURSE

JAN 12-13, 2019

NTUH International Convention Center
Taipei, Taiwan

Course Directors

Wei-Hsian Yin, MD
President, TSCI

Wen-Lieng Lee, MD
Chairman, Scientific Committee, TSCI

Tse-Min Lu, MD
Secretary General, TSCI

TTT 2019

臺灣介入性心臟血管醫學會
第七屆第一次公共醫療政策委員會會議紀錄

一、時　　間：107 年 5 月 2 日（星期三）PM 6：30

二、地　　點：台北市中正區忠孝西路一段 50 號 16 樓之 18 (學會會議室)

三、出席人員：〈主　委〉趙庭興

〈副 主 委〉鄭正一

〈委　員〉張恒嘉、陳鴻毅、黃群耀、謝敏雄、蘇正煌、陳郁志

四、請假人員：〈委　員〉王宇澄、詹貴川、朱志生、馬光遠、鍾昌峯

五、列席人員：殷偉賢理事長

〈秘 書 處〉盧澤民秘書長、秘書：林佳慧 (請假)、彭瑋婷、賴瑋儀 (紀錄)

六、議程：

提案一：確認本委員會組織簡則及 107-108 年度計劃。

說明：1. 本委員會原組織簡則 (略)。

2. 第七屆趙庭興主委擬訂之未來工作計劃：

1) 有關衛生福利部與中央健康保險署來文之內容討論與回覆。

2) 理事長交辦公共政策相關事項之推動方針討論與制定。

3) 新技術與新醫材申請給付事宜討論及建議。

4) 統整會員不合理健保給付之反應意見與制定回覆方針。

5) 有關醫院評鑑 , 評定 , 認證等相關條文修訂討論。

6) 推派委員代表參與中央衛生主管機關或相關醫學會之政策制定諮詢會議。

7) 針對社會重大議題研擬本會正式回應或新聞稿。

8) 其他與公共醫療政策相關事項。

決議：本委員會 107-108 年度工作計劃依本屆主委所擬執行。

提案二：結構性心臟病委員會傅雲慶主委於第七屆第二次理監事聯席會臨時動議中提出關於向健保署爭取同次導管做多種治療的 DRG、心臟內超音波等新技術治療的健保給付事宜。

說明：目前先天性心臟病的介入治療有許多項目已列入 DRG，如心房中膈缺損、開放性動脈導管、肺動脈瓣狹窄等，病人有時會同時有多重疾病如心房中膈缺損合併開放性動脈導管，需兩種以上治療或心房中膈缺損有多個缺損需多個特材及治療，這些處置可以同一次心導管治療，但依目前的 DRG 申報勢必不符成本，若分兩次手術對病人也不公平，建議健保署訂定合理的 DRG 給付以嘉惠患者。

決議：以「將特材拉出 DRG 分別申報」面向著手撰寫公文，相關公文請陳郁志委員協助草擬。

提案三：王光德理事於第七屆第二次理監事聯席會會議中提出，由本會行文至健保署將針對 LAA Occluder 執行治療之規範限制執行中，醫院條件改為醫院有外科醫師 on site 即可。

說明：現行規範執行 Left Atrial Appendage Occluder 之醫院條件為需有心導管室設備同時具有心臟內、外科訓練機構資格。

決議：先查詢國外文獻或治療指引對於執行此術式之規範，以「在偏遠地區執行 LAAO 之醫院條件是否能修改為只要有外科醫師 On Site 即可，不一定須具備外科訓練機構資格」面向著手撰寫公文，相關公文請蘇正煌委員協助草擬。

提案四：行文至衛生署表示學會立場為希望顱內急性腦中風之顱內的緊急介入治療，除了神經專科領域醫師外，亦能開放由受認證的心臟內科專科醫師接受訓練與執行治療，並建立一套神經科與心臟科醫師共同照護的治療模式。

說明：國際暨兩岸交流委員會高憲立委於第七屆第二次理監事聯席會會議中提出討論，經理事會議討論後建議於公共政策委員會討論後行文至衛福部。

決議：請陳鴻毅委員協助修改去年發出的公文後再次行文衛生福利部。

提案五：DRG 4.0 已公告於 107 年 7 月正式上線，對於心血管介入之給付有重大影響，徐中和理事建議本會尋求多方協助，以爭取會員權益。

說明：參閱螢幕會議簡報 (略)。

決議：請趙庭興主委針對 DRG4.0 版（第 3~5 階 DRG）有疑義處擬具公文，行文衛福部並副知林靜儀立委國會辦公室。

提案六：討論本年度預訂召開會議次數、下次召開會議日期及委員們方便出席會議之週間時間。

說明：參閱會議當天委員方便出席會議週間時間之調查彙整。

決議：以多數委員選取周二為主。

八、臨時動議

1. 推派代表出席行政院原子能委員會「心導管與血管攝影 X 光機之醫療曝露品保作業納法試辦計畫」專家會議。

決議：請醫事人員委員會李素珠主委協助派代表出席。

2. 行文建議健保給付急性冠心症患者使用雙重抗血小板藥物治療由持續 9 個月延長至 12 個月。

決議：請鄭正一副主委協助撰寫公文。

九、散會

臺灣介入性心臟血管醫學會
第七屆第一次財務委員會會議紀錄

一、時　　間：107 年 5 月 9 日（星期三）PM6：30

二、地　　點：TSCI 秘書處會議室 (地址：台北市中正區忠孝西路一段 50 號 16F-18)

三、出席人員：〈主　委〉黃啟宏

〈副 主 委〉施俊明

〈委　員〉林佳濱、許育誠、郭李堂、陳鈜忠、彭明正、蔡天堯、劉尊睿

四、請假人員：陳隆景、黃文彬、鄭曉揚、林俊呈

五、列席人員：曾賜福會計師

〈秘 書 處〉盧澤民秘書長，秘書：林佳慧 (請假)、彭瑋婷、賴瑋儀 (記錄)

六、報告事項：

曾賜福會計師報告：106 年度財務報表 - 收支決算表、資產負債表、現金出納表、基金收支表、財產目錄 (略)

七、議程

提案一：確認本委員會組織簡則及本年度計劃。

說明：1. 本委員會組織簡則 (略)。

2. 第七屆黃啟宏主委擬訂之未來工作計劃：

(1) 審閱及監督年度各類財務報表，年度收支預算表與帳務及財物之運用。

(2) 配合及協助會計師完成學會 107-108 年度預算審查，結算申報及各類給付扣繳申報等作業。

(3) 每個月份進行在職人員薪資結算及發放審查作業。

(4) 配合及協助各委員會進行財務預算與統整，經費之籌措與運用，及相關會議財務之調度與審查，以利學會會務之進展與開拓。

(5) 配合及協助理事長及秘書處之財務預算概念，有效及審慎運用財源，造福所有會員。

決議：1. 無異議通過本委員會組織簡則。

2. 本委員會 107-108 年度工作計劃依本屆主委所擬執行。

提案二：確認提列「準備基金」之百分比。

說明：依「社會團體財務處理辦法」第 20 條規定提列「準備基金」。

決議：106 年度財務結算後，從經費收入中提撥 2% 金額做為基金，提送理監事會追認。

提案三：討論會員之各項收費標準是否調整。

說明：1. 本會財務管理辦法第貳條及備註三 (略)。

2. 國外醫師：會前 300 美金、現場 500 美金

3. 國外醫事：會前 150 美金、現場 250 美金

		認證訓練 研討會	一般教育 訓練研討會	年度國際研討會 (TTT)(2天)
會前報名	會員 - 醫師	1,000	300	500
	會員 - 醫事 / fellow	200	100	200
	非會員 - 醫師	2,000	600	1,000
	非會員 - 醫事	400	200	400
現場報名	會員 - 醫師	2,000	300	500
	會員 - 醫事 /fellow	400	100	200
	非會員 - 醫師	4,000	600	1,000
	非會員 - 醫事	800	200	400

決議：各項收費標準維持不變。

提案四：未來醫師 / 醫事人員申請加入會員時，是否不繼續沿用過去抵扣方式 (即入會後，其過去以非會員身分繳交的報名費可用來抵扣入會費)。

說明：因現行新入會的會員能以過去參加的研討會報名費抵扣入會費，但有許多會員反映，如此對於先入會的會員的權益受損。

決議：為維護會員權益，即日起提出入會申請者將不繼續此抵扣方式。

提案五：討論未來學會委員會會議改以視訊會議方式進行後，委員出席費支付相關事項。

說明：第七屆第二次理監事聯席會中決議：「未來除了理監事會議、甄審委員會及其他各委員會第一次會議維持實體會議，其餘委員會原則上將以視訊會議方式進行，並參與委員每次支付出席費 800 元，出席費採累計次數年付。」

決議：以每年年會做為前一年出席費支付之結算日。

提案六：討論本年度預訂召開會議次數、下次召開會議日期及委員們方便出席會議之週間時間。

說明：參閱會議當天委員方便出席會議週間時間之調查彙整。

決議：先暫定 11 月倒數兩周擇一日，後續會再以調查方式選擇最多委員可以的日期。

八、臨時動議

九、散會

臺灣介入性心臟血管醫學會
第七屆第一次國際暨兩岸交流委員會會議紀錄

一、時　　間：107 年 5 月 29 日（星期二）PM6：30

二、地　　點：台北市中正區忠孝西路一段 50 號 16 樓之 18 (學會會議室)

三、出席人員：〈主　委〉高憲立

〈委　員〉王志鴻、吳志成、陳鴻毅、劉如濟、劉俊傑、謝慕揚、曹承榮、王光德、陳志成

四、請假人員：〈委　員〉方慶章、郭風裕、顧博明

五、列席人員：〈秘 書 處〉盧澤民秘書長、秘書：林佳慧 (記錄)、彭瑋婷、賴瑋儀

六、報告事項：

七、議程

提案一：確認本委員會組織簡則及 107-108 年度計劃。

說明：1. 本委員會原組織簡則 (略)

2. 前屆委員會擬定之 105-106 年度工作計劃為：

(1) 在本會年會的會議上廣邀來自兩岸及全球知名之各地的介入專家參與，持續提升本會之水準，期能擴大規模，吸引更多的國外人士參加。

(2) 促進並配合學會任務指派，參與各國大型的會議。

(3) 協助爭取與其他新的國際會議合作，如印度 NIC 會議。

(4) 積極參與 AICT 2016 之籌辦。

(5) 繼續定期赴大陸參與各項重要會議如南方會、東方會、錢江會、南京分岔病變會議、廈門兩岸年度論壇等等。

(6) 繼續加強與國際介入專家或機構的學術交流及研究合作。

3. 第七屆高憲立主委擬訂之未來工作計劃：

(1) 在本會年會的會議上廣邀來自全球及兩岸知名的介入專家參與，持續提升本會之水準，期能擴大規模，吸引更多的國外人士參加。

(2) 促進並配合學會任務指派，參與各國大型的會議。

(3) 協助爭取及建立與其他國際會議的合作，提升學會及國內醫師的國際曝光。

(4) 繼續定期赴大陸參與各項重要會議如南方會、東方會、錢江會、南京分岔病變會議、廈門兩岸年度論壇等等。

(5) 繼續加強與國際介入專家或機構的學術交流及研究合作。

決議：1. 無異議通過本委員會組織簡則。

2. 本委員會 107~108 年度工作計畫依本屆主委所擬執行。

提案二：討論本屆國際暨兩岸會議的參與及學術合作交流內容。

說明：1. 現有國際暨兩岸會議的參與及學術合作交流

a) 韓國 - TCTAP

b) 日本 - JET

c) 日本 - CVIT

d) 印度 - NIC/APVIC
e) 中國 - 錢江國際心血管病會議暨浙江省心血管病年會 (QICC)
f) 美國 - TCT
g) 日本 - CCT
h) 中國 - 海峽國際心血管病學論壇 (CSCIF) . 廈門國際心血管病介入論壇

2. 討論是否有建議增減的會議

決議：1. 目前合作的會議已不少，暫時維持目前與現有各會議的合作型態，不另新增。

提案三：近期國際暨兩岸會議 joint session 及合作。

說明：1. 日本 TTT@CVIT：2018.08.03 16:00-17:30 ，節目表請參見螢幕 (略)。
Topic: Current status of CTO PCI in Taiwan and Japan

2. 中國 TTT@QICC：節目表請參見螢幕 (略)。
2018.09.07 2 小時 Topic: Structural Heart
2018.09.08 2 小時 Topic: Chip PCI

3. 美國 TCT：節目表請參見螢幕 (略)。
2018.09.22 08:30-10:00 International Sessions (Taiwan, Japan, Thailand, Indonesia)
2018.09.22 14:00-16:00 Regional Session:The Best of Intervention From Asia-Pacific

4. 中國海峽國際心血管病學論壇 (CSCIF) . 廈門國際心血管病介入論壇：
王焱院長邀請台灣協助兩個 site 轉播，徵求各院意願。

決議：1. TTT@CVIT 依目前節目安排再新增一個演講，邀請王志鴻副主委擔任講師。每個演講 15 分鐘，共五分鐘討論。

2. QICC 9/8 場次因王志鴻副主委無法出席，改邀陳志成委員主持本日時段，劉如濟委員、謝慕揚委員擔任 panelists。講師由台灣和中國各出三位，請中國從未定的兩個題目擇一後，再確認台灣講師。

3. TCT joint sessions 依目前節目安排進行。

4. 今年廈門會時間為 11/22-25，台灣轉播醫院推薦台東馬偕並徵詢林口長庚或台中榮總意願。

提案四：討論本年度預訂召開會議次數、下次召開會議日期及委員們方便出席會議之週間時間。

說明：參閱會議當天委員方便出席會議週間時間之調查彙整。

決議：擬定於 8 月 21 日 (W2) 以視訊方式召開第二次委員會，並建議一年至少召開一次實體會議。

八、臨時動議

九、散會

臺灣介入性心臟血管醫學會
第七屆第一次結構性心臟病委員會會議紀錄

一、時　　間：107 年 5 月 31 日（星期四）18：30

二、地　　點：臺灣介入性心臟血管醫學會會議室(地址：台北市忠孝西路一段50號16樓之18)

三、出席人員：〈主　委〉傅雲慶

〈副 主 委〉邱俊仁

〈委　員〉李必昌、林茂欣、林銘泰、陳嬰華、蔡佳醍、王玠能、劉嚴文、黃建富

四、請假人員：〈委　員〉李應湘、曹殿萍、鍾宏濤

五、列席人員：殷偉賢理事長

〈秘 書 處〉盧澤民秘書長，秘書：林佳慧、彭瑋婷 (紀錄)、賴瑋儀

六、報告事項：

七、議程：

提案一：確認本委員會組織簡則及 107~108 年度計劃。

說明：1. 參閱本委員會組織簡則 (略)。

2. 第七屆傅雲慶主委擬訂之未來工作計劃如下：

(1) 舉辦「心房中膈缺損認證課程暨卵孔腦中風研討會」：6/23 振興醫院。

(2) 年底舉辦「心室中膈缺損認證課程」。

(3) 舉辦肺動脈置換、二尖瓣介入及左心耳封堵的講習。

(4) 爭取健保局給付，如同次導管做多種治療的 DRG、心臟內超音波、等新技術治療的給付等。

(5) 推動”結構性心臟病介入治療專科醫師”及各種不同治療項目的認證，以提昇品質。

決議：1. 無異議通過本委員會組織簡則。

2. 本委員會 107-108 年度工作計劃依本屆主委所擬執行。

3. 針對工作計畫第四點，107.5.2 第七屆第一次公共醫療政策委員會提案二討論後決議以「將特材拉出 DRG 分別申報」面向著手撰寫公文，相關公文請公共醫療政策委員會陳郁志委員協助擬寫。目前公文已擬好確認後將行文至健保署。

4. 針對工作計畫第五點，107.4.17 第七屆第一次甄審委員會提案四針對專科醫師甄審增設證書種類之事宜，決議因結構性心臟病牽涉甚廣，煩請傅雲慶主委擬訂相關甄試及認證草案，待提出後再深入探討評估此提案是否可行。此議題將於下次會議提出請各委員討論。

提案二：107~108 年辦理結構性心臟病教育課程時間及地點規劃。

說明：1. 第六屆期間共舉辦結構性心臟病相關繼續教育課程如下：

(1) 105.10.16 Intervention for structural heart diseases: Where are we now?
地點：臺大醫學院 301 講堂

(2) 106.08.12 Transcatheter Closure of VSD 地點：
中國醫藥大學附設醫院癌症中心大樓

(3) 106.11.25 Percutaneous LAA Closure Training Course
地點：臺大醫學院 102 講堂

2. 本會今年度已確定研討會日期為：
5/5、6/9、6/23、7/8、7/28、8/12、8/19、9/15-9/16 (秋季會)、10/20、11/17、12/15、12/22、108/1/12-1/13(TTT 2019)、4/13。

決議：1. 擬定於 108 年 3 月舉辦一場結構研討會，看看是否有機會和 3/28-3/31 的 CIT 2019 合作並於下次委員會再進一步討論。

2. 請學會和 SingLIVE 接洽看看明年是否有合作機會。

提案三：學會定於 6/23(六) 舉辦「Transcatheter Closure of ASD and PFO 研討會」。

說明：講師座長皆已邀約完畢，請參閱節目表 (略)。

決議：無異議通過。

提案四：討論 TTT 2019 結構性心臟病節目主題及初步規劃。

說明：1. TTT 2019 時間為 108 年 1 月 12-13 日。

2. 請規劃 1.5 - 2 個小時的節目內容，請委員協助討論節目主題、初步安排及確認欲邀請外賓，以呈理事長、秘書長及學術委員會確認。

決議：1. 擬定籌備半天的 Live Demo 節目內容，預定 3 個 Demo Site 各準備 2 個 Demo Case，共轉播 6 個 Case。

2. Demo 時間尚待學術委員會安排確認，目前暫定於 108 年 1 月 13 日上午，地點：台大國際會議中心 Room401。

3. 外賓部分學會已預計邀請 Dr. Alain G. Cribier、Dr. Eberhard Grube、Dr. Yuval Binur，可再邀請 2-3 位結構方面外賓。

提案五：建議健保署修正診療項目代碼 33112B 及 33114B 有關經由心導管治療開放性動脈導管的適應症及禁忌症的條文，以嘉惠病人。

說明：由於器材及技術的進步，建議修改開放性動脈導管病人體重的適應症及相關禁忌症，以嘉惠病人、免除開刀之苦。請參閱附件 (略)。

決議：同意，將由傅雲慶主委擬寫公文行文衛福部。

提案六：討論本年度預訂召開會議次數、下次召開會議日期及委員們方便與會之週間時間。

說明：參閱現場調查委員方便出席會議之週間時間彙整表。

決議：擬定 10 月 11 日 (W4) 以視訊會議方式召開第二次委員會。

八、臨時動議

九、散會

臺灣介入性心臟血管醫學會
第七屆第一次醫事人員委員會會議紀錄

一、時　　間：107 年 6 月 27 日（星期三）18：30

二、地　　點：TSCI 秘書處會議室 (地址：臺北市忠孝西路一段 50 號 16 樓之 18)

三、出席人員：〈主　委〉李素珠

〈副 主 委〉黃銘玲

〈委　員〉林素楓、郭宜蘭、曾欽煇、朱光華、杜文桂、李庚原、邵雅芬、王鳳花、林見財、林瓊枝、黃漢龍

四、請假人員：無

五、列席人員：殷偉賢理事長

〈秘 書 處〉盧澤民秘書長、林佳慧、彭瑋婷 (紀錄)、賴瑋儀

六、報告事項：

七、議程：

提案一：確認本委員會組織簡則及 107-108 年度計畫。

說明：1. 參閱本委員會組織簡則 (略)。

2. 前屆委員會擬定之 105-106 年度工作計畫為：

(1) 鼓勵醫事與護理人員踴躍加入學會並熱烈參加學術活動。

(2) 協辦醫事人員繼續教育課程，並協助新進醫師同時取得專業知識。

(3) 擴展游離輻射防護觀念，讓病人和醫師有最安全的輻射環境。

3. 第七屆李素珠主委未來工作計劃：

(1) 於秋季會及年會舉辦醫事人員教育訓練課程，以提升醫事人員專業知識及技能。

(2) 配合學會各項會務活動。

決議：1. 無異議通過本委員會組織簡則。

2. 本委員會 107-108 年度工作計劃依本屆主委所擬執行。

提案二：討論 107 年度醫事人員教育訓練課程安排。

說明：1. 2018 秋季會將於 107 年 9 月 15-16 日於高雄義大皇家酒店舉辦。

2. 107 年度醫事人員繼續教育課程預訂於 2018 秋季會星期日上午舉辦。

3. 參考過去節目規劃：106 年度醫事人員繼續教育課程節目表 (略)

105 年度醫事人員繼續教育課程節目表 (略)

決議：1. 擬於 9 月 16 日秋季會星期天 08:20AM - 12:00PM 舉行。

2. 初擬節目規劃如下 :

時 間	講 師	主 題	座 長
08:20	OPENING 殷偉賢 理事長		
08:25	蔡政廷 台北馬偕	血管內超音波概論與臨床應用判讀	黃銘玲
08:50	盧炯睿 中國附醫	介入性周邊導管診療在下肢動脈阻塞應用醫材概述	李庚原
09:15	王光德 台東馬偕	iFR & FFR 概論與臨床應用判讀	林見財
09:40	朱光華 中國附醫	心導管室從業人員對於輻射防護應有之認知	邵雅芬
10:05	Coffee Break		
10:20	李慶威 台北榮總	經導管二尖瓣膜修補術 (Mitraclip)	郭宜蘭
10:45	曹殿萍 振興醫院	經導管主動脈瓣膜植入術	曾欽輝
11:10	顧博明 柳營奇美	OCT 概論與臨床應用判讀	黃漢龍
11:35	朱光華 中國附醫	心導管 X 光機醫療曝露品保作業納法試辦計畫說明	杜文桂
12:00	CLOSING 李素珠 主委		

提案三：討論本年度是否規劃「醫事人員 ROTA 課程」。

說明：1. 第六屆教育委員會時提及是否開放現有的 ROTA 認證給醫事人員參加，但考量醫事人員的課程方向及內容略有差異，故傾向另外舉行，再請委員們討論課程安排之必要性。

2. 請參閱附件 2017 年「醫事人員 ROTA 訓練課程」節目表 (略)。

決議：1. 擬於秋季會星期天醫事人員教育訓練課程後 12:10PM - 15:00PM 舉行。

2. 本會醫事人員優先參加。

3. 不限人數，僅限會前報名，不開放現場報名。

4. 初擬節目規劃如下 :

時 間	講 師	主 題	座 長
12:10	OPENING 殷偉賢 理事長		
12:15	王志鴻 花蓮慈濟	冠狀動脈旋轉研磨術 - 注意事項	林素楓
12:35	李文領 台中榮總	冠狀動脈旋轉研磨術 - 併發症暨處置對策	林瓊枝
12:55	顧博明 柳營奇美	冠狀動脈旋轉研磨術 - 探討鈣化影像特徵：(MDCT calcium scoring, 斷層掃描判讀 , Angio, IVUS, OCT)	王鳳花
13:15	Break		
13:25 | 15:00	王志鴻、王鳳花 李文領、李庚原 顧博明、黃漢龍	Rotablator Simulator- Hands-on Simulator 1 Simulator 2 Simulator 3	

提案四：討論 TTT 是否另外針對醫事人員舉辦教育訓練課程。

說明：請參閱附件 TTT 2018「Nurse/Technician Symposium」節目表 (略)。

決議：TTT 2018 醫事人員繼續教育課程內容可用報 CASE 方式以醫事人員角度分享經驗也可鼓勵年輕一輩參加，另外可在 TTT 設 Learning Center 找 2-3 間廠商贊助設備器材給醫事人員實際動手操作，節目規畫請主委先擬出後於下次委員會提出討論。

提案五：討論本年度預訂召開會議次數、下次召開會議日期及委員們方便與會之週間時間。

說明：參閱現場調查委員方便出席會議之週間時間彙整表。

決議：暫定 10 月 3 日 (W3) 以視訊會議方式召開第二次委員會。

八、臨時動議

(一)〈殷偉賢理事長〉醫事人員委員會是否未來能和其他國外學會有 join 機會以增加學術交流並汲取國外經驗。

決議：同意，各委員若有管道或建議規劃請於下次委員會提出。

九、散會

本期案例

【案例】

A 75-year-old man presented with chest tightness and dyspnea on exertion for months. The stress test showed positive result and he was admitted for elective coronary angiogram. The ECG and CXR upon admission were shown on Figure 1 and Figure 2. Physical examination showed symmetric bilateral radial pulse. Cardiac catheterization was performed through left radial artery. Slight tortuous left subclavian artery was first found during delivery of the Terumo wire with left Judkins catheter. Selective angiography was performed at left subclavian artery (Figure 3A and 3B). After delivering the left Judkins catheter to the usual position, we could not engage the left coronary artery. Pullback aortography was performed by left Judkins catheter (Figure 3C and 3D).

Figure 1

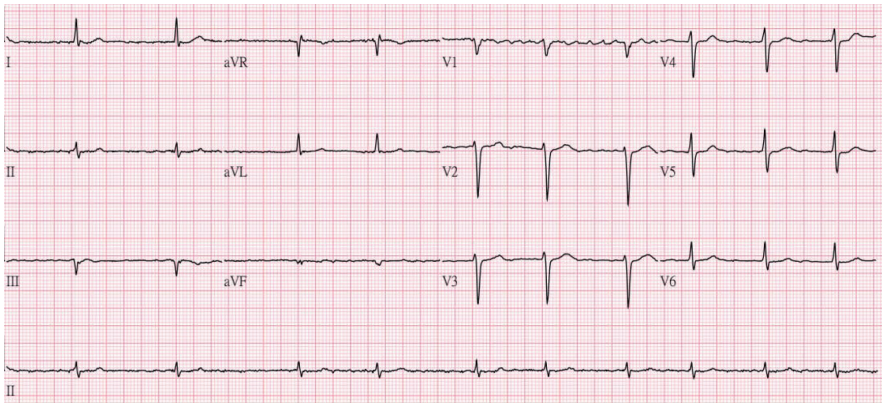


Figure 2

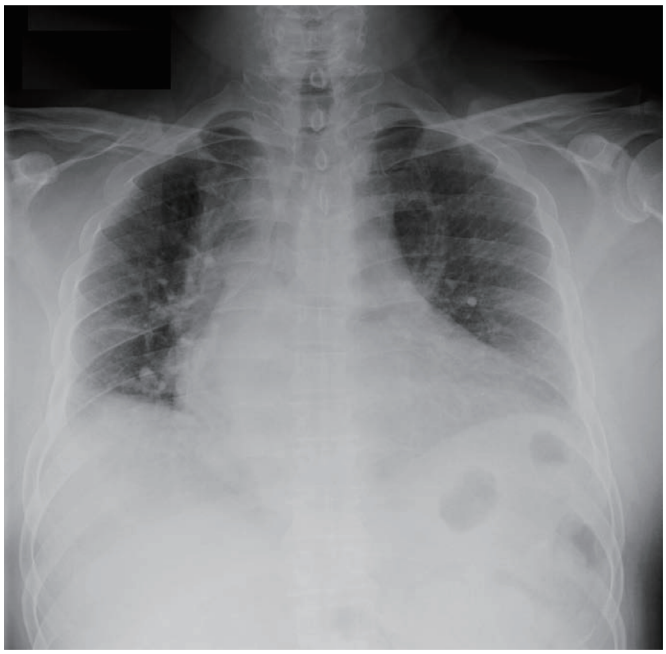


Figure 3A AP view

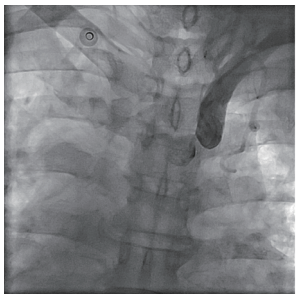


Figure 3B Lateral view

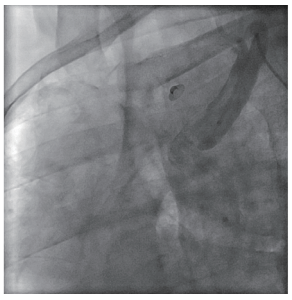


Figure 3C AP view

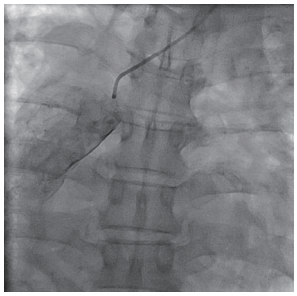
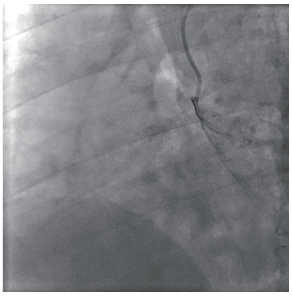


Figure 3D Lateral view



【試問】

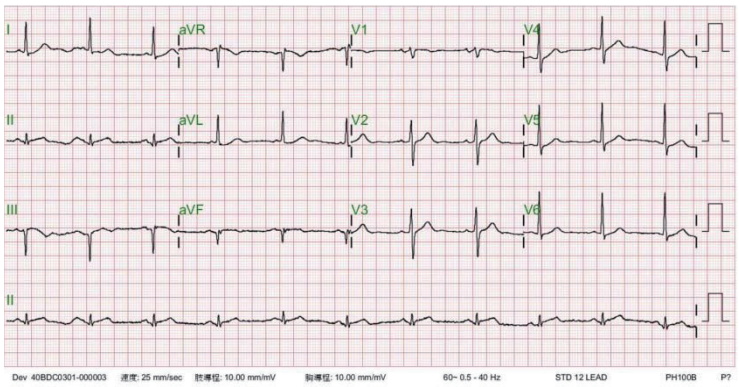
What is the diagnosis?

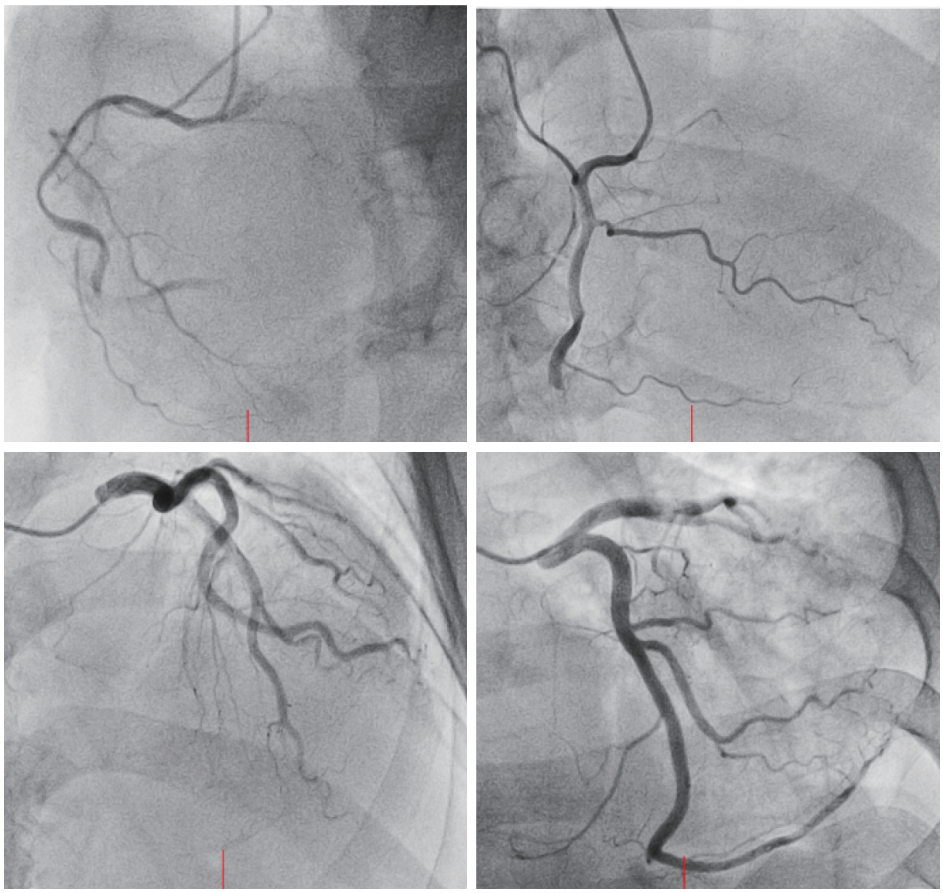
臺大醫院 蔡承烜醫師

上期解答

【案例】

41 歲男性，因急性胸痛至急診就醫，心電圖如圖，心肌酵素顯示 CK:2860 IU/L(38 – 397)，Troponin-I: >80.000 ng/mL (Cutoff:<0.5,URL:0.04)，CKMB :124.0 ng/mL (<5.4)，診斷為 NSTEMI 入住加護病房，住院後病患仍持續胸痛，因此安排心導管檢查，心導管影像如圖 :





【試問】

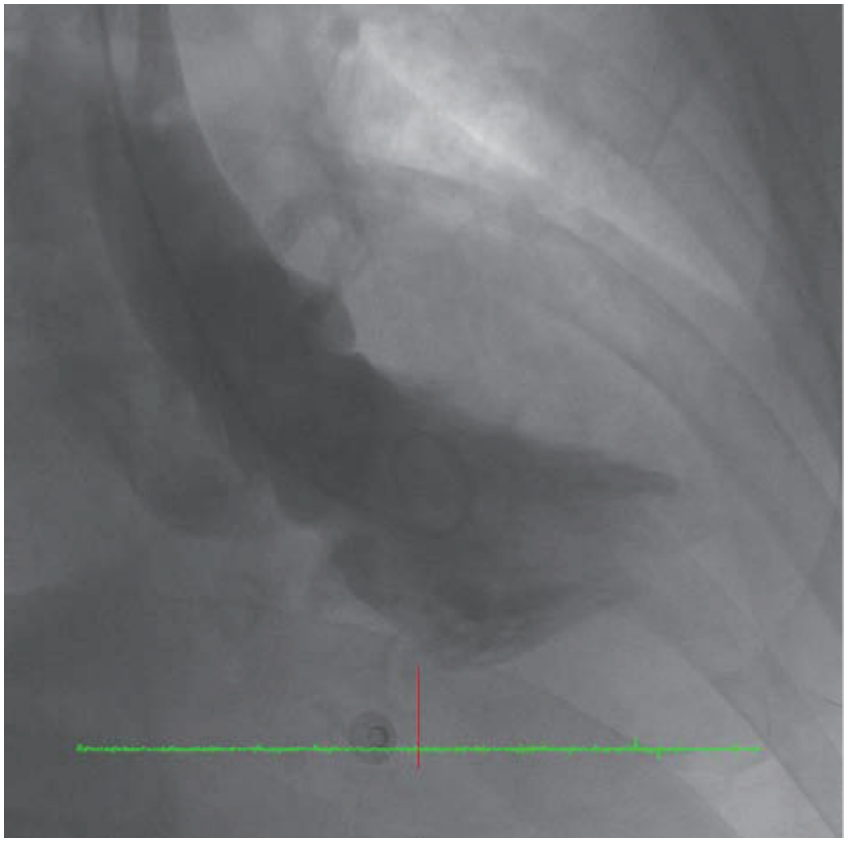
可能診斷為何？

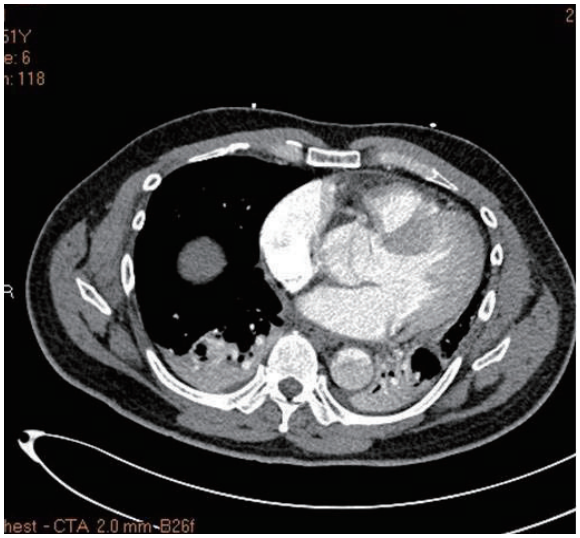
下一步該如何處置？

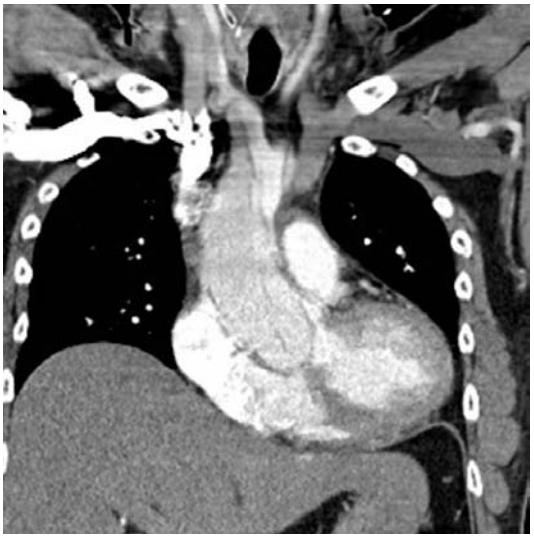
馬偕紀念醫院心臟內科 林岳鴻醫師

【答案】

RCA 診斷為 spiral dissection，bedside echocardiography 顯示為 severe AR，LVG 顯示 ascending aortic dissection，斷層掃描顯示為 ascending aortic dissection，因此緊急會診心臟外科 for surgical treatment。







High-Sensitivity Troponins and Outcomes After Myocardial Infarction

Maria Odqvist, et al.

J AM COLL CARDIOL. 2018 JUN 12;71(23):2616-2624

BACKGROUND

It remains unknown how the introduction of high-sensitivity cardiac troponin T (hs-cTnT) has affected the incidence, prognosis, and use of coronary angiographies and revascularizations in patients with myocardial infarction (MI).

OBJECTIVES

The aim of this study was to investigate how the incidence of MI and prognosis after a first MI was affected by the introduction of hs-cTnT.

METHODS

In a cohort study, the authors included all patients with a first MI from the Swedish National Patient Registry from 2009 to 2013. Cox regression was used to calculate hazard ratios (HRs) with 95% confidence intervals (CIs) for risk of all-cause mortality, reinfarction, coronary angiographies, and revascularizations in patients with MI diagnosed using hs-cTnT compared with those diagnosed using conventional troponins (cTn).

RESULTS

During the study period, 47,133 MIs were diagnosed using cTn and 40,746 using hs-cTnT. The rate of MI increased by 5% (95% CI: 0% to 10%) after the introduction of hs-cTnT. During 3.9 ± 2.8 years of follow-up, there were 33,492 deaths, with no difference in the risk of all-cause mortality (adjusted HR: 1.00; 95% CI: 0.97 to 1.02). There were, in total, 15,766 reinfarctions during 3.1 ± 2.3 years of follow-up, with the risk of reinfarction reduced by 11% in patients diagnosed using hs-cTnT (adjusted HR: 0.89; 95% CI: 0.86 to 0.91). The use of coronary angiographies (adjusted HR: 1.16; 95% CI: 1.14 to 1.18) and revascularizations (adjusted HR: 1.13; 95% CI: 1.11 to 1.15) increased in the hs-cTnT group.

CONCLUSIONS

In a nationwide cohort study including 87,879 patients with a first MI, the introduction of hs-cTnT was associated with an increased incidence of MI, although with no impact on survival. We also found a reduced risk of reinfarction alongside increased use of coronary angiographies and revascularizations.

高敏感性心肌旋轉蛋白於心肌梗塞後之預後影響

編譯：臺大醫院 心臟內科 林重佑醫師

摘要

背景

對心肌梗塞患者檢測高敏感性心肌旋轉蛋白 (high-sensitivity cardiac troponin T, hs-cTnT)，如何影響心肌梗塞發生率、疾病預後、接受冠狀動脈攝影與冠狀動脈血管重建術治療的比例，目前所知有限。

研究目的

本研究探討檢測高敏感性心肌旋轉蛋白，對於第一次心肌梗塞患者之心肌梗塞發生率與其預後之影響。

方法

此世代研究分析瑞典國家病人註冊系統 (Swedish National Patient Registry) 中自 2009 至 2013 年間首次診斷心肌梗塞的病人。利用 Cox 迴歸模式分析檢測高敏感性心肌旋轉蛋白 T 診斷心肌梗塞的族群對比檢測傳統的心肌旋轉蛋白族群，於全死因死亡、再次心肌梗塞、接受冠狀動脈攝影以及接受冠狀動脈血管重建術的比例之風險比值 (Hazard ratio) 與 95% 信賴區間 (95% confidence intervals)。

結果

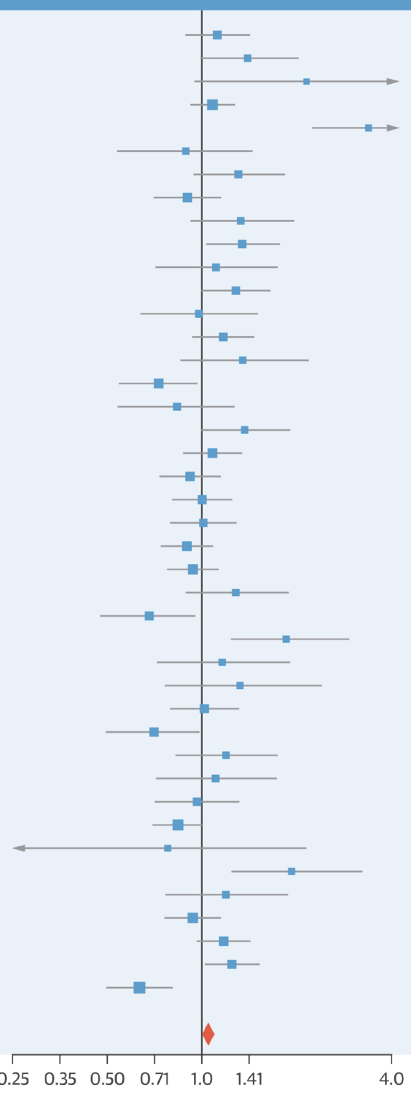
在研究的區間內，共有 47,133 位心肌梗塞的病人是使用傳統的心肌旋轉蛋白所診斷，另外有 40,746 個病人則是使用高敏感性心肌旋轉蛋白 T 診斷。自從引進使用高敏感性心肌旋轉蛋白 T 後，診斷心肌梗塞的比例增加了 5% (95% CI: 0% ~ 10%)。經過 3.9 ± 2.8 年的追蹤，共有 33,492 人死亡，但兩個族群間於全因死亡率無顯著差異 (adjusted HR: 1.00; 95% CI: 0.97 ~ 1.02)。經 3.1 ± 2.3 年的追蹤，總共 15,766 位病患發生再次心肌梗塞，研究發現使用高敏感性心肌旋轉蛋白 T 診斷的病人族群中，再次發生心肌梗塞的風險機率下降 11% (adjusted HR: 0.89; 95% CI: 0.86 ~ 0.91)。同時研究也發現使用高敏感性心肌旋轉蛋白 T 診斷的心肌梗塞病人有著較高的比例接受冠狀動脈攝影 (adjusted HR: 1.16; 95% CI: 1.14~1.18)，以及接受冠狀動脈血管重建術 (adjusted HR: 1.13; 95% CI: 1.11 ~ 1.15)。

結論

在這個全國性的世代研究中總共納入了 87,879 位首次診斷心肌梗塞的病人。我們發現，使用高敏感性心肌旋轉蛋白 T 來診斷心肌梗塞的病人有著較高的心肌梗塞診斷率，然而對於存活率並沒有影響；此外我們也發現這群病人有著較低的再次心肌梗塞風險，較高的冠狀動脈攝影的檢查率與冠狀動脈血管重建術的治療率。

CENTRAL ILLUSTRATION Sensitive Troponins and Prognosis After MI

Date	Hospital	hs-cTnT/cTn	RR (95% CI)
08/10/2009	Sundsvall	151/135	1.12 (0.89-1.41)
08/10/2009	Örnsköldsvik	74/53	1.40 (0.99-2.02)
12/02/2009	Landskrona	15/7	2.14 (0.95-7.09)
12/02/2009	Lund	314/291	1.08 (0.92-1.27)
01/14/2010	Eksjö	81/24	3.38 (2.24-5.75)
01/27/2010	Lycksele	31/35	0.89 (0.54-1.44)
01/27/2010	Skellefteå	82/63	1.30 (0.94-1.83)
01/27/2010	Umeå	122/136	0.90 (0.70-1.14)
02/22/2010	Hässleholm	65/49	1.33 (0.92-1.95)
02/22/2010	Kristianstad	130/97	1.34 (1.03-1.76)
02/22/2010	Ängelholm	42/38	1.11 (0.71-1.74)
02/25/2010	Helsingborg	142/111	1.28 (1.00-1.65)
03/01/2010	Arvika	43/44	0.98 (0.64-1.50)
03/01/2010	Karlstad	167/143	1.17 (0.94-1.46)
03/01/2010	Torsby	43/32	1.34 (0.86-2.18)
05/03/2010	Östersund	83/114	0.73 (0.54-0.96)
06/11/2010	Motala	40/48	0.83 (0.54-1.27)
06/11/2010	Norrköping	90/66	1.36 (1.00-1.89)
06/14/2010	Linköping	179/166	1.08 (0.87-1.33)
11/01/2010	Blekinge	154/168	0.92 (0.74-1.14)
12/06/2010	Gävle	164/164	1.00 (0.80-1.24)
12/08/2010	Huddinge	134/133	1.01 (0.79-1.28)
12/08/2010	Karolinska	204/228	0.89 (0.74-1.08)
12/08/2010	Söder	214/229	0.93 (0.77-1.13)
12/08/2010	Södertälje	64/50	1.28 (0.89-1.88)
01/01/2011	Bollnäs	55/81	0.68 (0.47-0.95)
01/18/2011	Gällivare	61/33	1.85 (1.23-2.93)
01/18/2011	Kalix	37/32	1.16 (0.72-1.89)
01/18/2011	Kiruna	29/22	1.32 (0.76-2.38)
01/18/2011	Sunderby	125/123	1.02 (0.79-1.31)
01/19/2011	Hudiksvall	57/81	0.70 (0.49-0.98)
01/20/2011	Piteå	63/53	1.19 (0.83-1.73)
05/01/2011	Oskarshamn	43/39	1.10 (0.71-1.72)
05/01/2011	Ystad	81/84	0.96 (0.71-1.31)
05/02/2011	Malmö	220/263	0.84 (0.70-1.00)
05/10/2011	Simrishamn	7/9	0.78 (0.24-2.13)
05/10/2011	Trelleborg	52/27	1.93 (1.24-3.22)
05/11/2011	Västervik	44/37	1.19 (0.77-1.87)
05/12/2011	Kalmar	182/195	0.93 (0.76-1.14)
09/30/2011	Danderyd	227/194	1.17 (0.97-1.42)
02/01/2012	Trollhättan	225/181	1.24 (1.02-1.52)
02/13/2013	S:t Göran	110/174	0.63 (0.49-0.80)
[−90;89]	**Total**	**4446/4252**	**1.05 (1.00-1.09)**



Odqvist, M. et al. J Am Coll Cardiol. 2018;71(23):2616-24.

▲高敏感性心肌旋轉蛋白與預後的關係

TABLE 1 Baseline Characteristics of All Patients in Sweden From 2009 to 2013 With a First MI in Relation to the Troponin Assay Used for Diagnosis

	All Patients (N = 87,879) (100%)	cTn (n = 47,133) (54%)	hs-cTnT* (n = 40,746) (46%)
Age, yrs	73.2 ± 13.0	73.7 ± 13.0	72.7 ± 13.0
Men	52,682 (60)	27,845 (59)	24,837 (61)
Prior stroke	9,792 (11)	5,510 (12)	4,282 (11)
COPD	5,385 (6)	2,882 (6)	2,503 (6)
Prior heart failure	9,025 (10)	5,148 (11)	3,877 (10)
Diabetes	14,191 (16)	7,597 (16)	6,594 (16)
Chronic kidney disease	2,466 (3)	1,292 (3)	1,174 (3)
Prior coronary angiography	3,661 (4)	1,713 (4)	1,948 (5)
Revascularization	4,998 (6)	2,560 (5)	2,438 (6)
Aspirin	27,192 (31)	14,932 (32)	12,260 (30)
$P2Y_{12}$ inhibitors†	1,882 (2)	925 (2)	957 (2)
Beta-blockers	29,756 (34)	16,354 (35)	13,402 (33)
ACE inhibitor/ARB	30,759 (35)	16,345 (35)	14,414 (35)
Statins	19,142 (22)	10,029 (21)	9,113 (22)

▲表 1 兩個實驗族群的背景數據

TABLE 2 Total Number of MIs and UA in Relation to Method Used for Troponin Measurement in Sweden From 2007 to 2013

	2007	2008	2009	2010	2011	2012	2013
MI							
Total MIs	33,380	31,731	29,712	29,621	28,641	28,123	25,787
Residents >20 yrs old	6,974,057	7,038,351	7,112,622	7,192,356	7,269,107	7,342,808	7,417,271
Incidence per 10,000 py	48	45	42	41	39	38	35
Length of stay, days	8.8 ± 11.5	8.5 ± 11.0	8.2 ± 10.5	8.0 ± 10.3	7.7 ± 10.2	7.4 ± 9.2	7.3 ± 9.1
MI diagnosed with cTn							
Total MIs	N/A	N/A	28,609 (96)	18,986 (64)	10,159 (35)	7,849 (28)	6,732 (26)
Length of stay, days	N/A	N/A	8.2 ± 10.5	7.9 ± 10.2	7.5 ± 10.2	7.2 ± 9.1	7.1 ± 9.4
MI diagnosed with hs-cTnT							
Total MIs	N/A	N/A	439 (1.5)	6,842 (23)	15,120 (53)	18,881 (67)	18,519 (72)
Length of stay, days	N/A	N/A	8.0 ± 8.2	7.8 ± 9.8	7.5 ± 10.1	7.5 ± 9.3	7.4 ± 9.1
MI diagnosed at hospitals with hs-cTnT, higher decision limit*							
Total MIs	N/A	N/A	664 (2.0)	3,793 (13)	3,362 (12)	1,393 (5.0)	536 (2.1)
Length of stay, days	N/A	N/A	10.2 ± 12.8	8.6 ± 11.4	9.2 ± 10.3	8.5 ± 8.7	8.5 ± 8.0
UA							
Total UA	7,224	6,598	6,110	5,581	5,505	5,299	5,028
Length of stay, days	9.1 ± 11.1	9.1 ± 11.2	8.5 ± 10.2	8.2 ± 9.8	8.4 ± 11.3	7.6 ± 8.8	7.5 ± 9.2
UA diagnosed at hospitals with cTn							
Total UA	N/A	N/A	5,903 (97)	3,075 (55)	1,540 (28)	1,056 (20)	962 (19)
Length of stay, days	N/A	N/A	8.5 (10.2)	7.2 (9.4)	7.0 (13.2)	6.2 (7.4)	5.9 (6.6)
UA diagnosed at hospitals with hs-cTnT							
Total UA	N/A	N/A	74 (1.2)	1,768 (32)	3,269 (59)	4,020 (76)	3,987 (79)
Length of stay, days	N/A	N/A	8.1 ± 7.8	9.5 ± 10.5	8.7 ± 10.3	7.9 ± 9.1	7.7 ± 9.1
UA diagnosed at hospitals with hs-cTnT, higher decision limit*							
Total UA	N/A	N/A	133 (2.2)	738 (13)	696 (13)	223 (4.2)	79 (1.6)
Length of stay, days	N/A	N/A	9.7 ± 13.0	9.1 ± 9.5	9.9 ± 10.8	7.9 ± 8.3	7.8 ± 6.7

▲表 2 2017 至 2013 年間，心肌梗塞與不穩定型心絞痛的族群資料

TABLE 3 Risk of All-Cause Mortality and Reinfarction in Patients With a First MI in Sweden From 2009 to 2013 in Relation to Troponin Assay Used

	All-Cause Mortality		Reinfarction*	
Year	cTn	hs-cTnT	cTn	hs-cTnT
2009				
MI patients, n	18,846	311	16,708	284
Events, n	9,037	123	4,198	49
1-yr absolute risk, %	22.3 (21.6-22.9)	18.6 (13.9-23.4)	15.5 (14.9-16.1)	9.5 (5.9-13.1)
Crude HR (95% CI)	1.00	0.80 (0.67-0.95)	1.00	0.66 (0.50-0.88)
Adjusted HR (95% CI)	1.00	0.87 (0.73-1.04)	1.00	0.69 (0.52-0.91)
2010				
MI patients, n	12,418	4,619	11,049	4,151
Events, n	5,459	1,902	2,588	886
1-yr absolute risk, %	22.1 (21.3-22.9)	20.8 (19.5-22.1)	15.3 (14.5-16.0)	14.5 (13.3-15.6)
Crude HR (95% CI)	1.00	0.93 (0.88-0.98)	1.00	0.91 (0.84-0.98)
Adjusted HR (95% CI)	1.00	0.95 (0.90-1.00)	1.00	0.93 (0.86-1.00)
2011				
MI patients, n	6,551	10,218	5,839	9,229
Events, n	2,662	3,619	1,206	1,759
1-yr absolute risk, %	22.3 (21.2-23.5)	19.2 (18.3-20.0)	15.0 (14.0-16.0)	13.8 (13.1-14.6)
Crude HR (95% CI)	1.00	0.85 (0.81-0.89)	1.00	0.91 (0.85-0.98)
Adjusted HR (95% CI)	1.00	0.98 (0.93-1.03)	1.00	0.97 (0.90-1.04)
2012				
MI patients, n	5,039	12,869	4,542	11,551
Events, n	1,711	4,183	848	1,973
1-yr absolute risk, %	20.8 (19.6-22.1)	20.6 (19.8-21.4)	14.2 (13.1-15.3)	13.4 (12.7-14.1)
Crude HR (95% CI)	1.00	0.95 (0.90-1.01)	1.00	0.91 (0.84-0.98)
Adjusted HR (95% CI)	1.00	1.06 (1.00-1.12)	1.00	0.96 (0.89-1.05)
2013				
MI patients, n	4,279	12,729	3,821	11,461
Events, n	1,246	3,550	625	1,634
1-yr absolute risk, %	20.8 (19.5-22.2)	19.5 (18.7-20.2)	15.1 (13.8-16.3)	12.9 (12.2-13.5)
Crude HR (95% CI)	1.00	0.95 (0.89-1.01)	1.00	0.86 (0.79-0.94)
Adjusted HR (95% CI)	1.00	0.99 (0.93-1.05)	1.00	0.89 (0.81-0.98)

▲表 3 兩個族群的全因死亡率與再梗塞率的比較

TABLE 4 Coronary Angiography and Revascularization Within 30 Days in Patients With a First MI From 2009 to 2013 in Sweden Diagnosed With hs-cTnT Versus cTnT

	Coronary Angiography		Revascularization	
Year	cTn	hs-cTnT	cTn	hs-cTnT
2007				
N	11,022	N/A	9,201	N/A
n/100 MIs	50	N/A	42	N/A
2008				
N	10,949	N/A	9,260	N/A
n/100 MIs	52	N/A	44	N/A
2009				
N	10,339	203	8,709	165
n/100 MIs	55	65	46	53
Crude HR (95% CI)	1.00	1.25 (1.08-1.43)	1.00	1.17 (1.00-1.37)
Adjusted HR (95% CI)	1.00	1.17 (1.02-1.35)	1.00	1.07 (0.92-1.25)
2010				
N	6,897	2,826	5,906	2,363
n/100 MIs	56	61	48	51
Crude HR (95% CI)	1.00	1.13 (1.08-1.18)	1.00	1.09 (1.04-1.14)
Adjusted HR (95% CI)	1.00	1.12 (1.08-1.17)	1.00	1.08 (1.03-1.13)
2011				
N	3,479	6,476	2,997	5,600
n/100 MIs	53	63	46	55
Crude HR (95% CI)	1.00	1.25 (1.20-1.30)	1.00	1.24 (1.19-1.30)
Adjusted HR (95% CI)	1.00	1.16 (1.12-1.21)	1.00	1.13 (1.08-1.19)
2012				
N	2,880	8,360	2,456	7,100
n/100 MIs	57	65	49	55
Crude HR (95% CI)	1.00	1.19 (1.14-1.24)	1.00	1.16 (1.11-1.22)
Adjusted HR (95% CI)	1.00	1.16 (1.11-1.21)	1.00	1.12 (1.07-1.17)
2013				
N	2,377	8,357	2,133	7,216
n/100 MIs	56	66	50	57
Crude HR (95% CI)	1.00	1.24 (1.19-1.30)	1.00	1.17 (1.11-1.22)
Adjusted HR (95% CI)	1.00	1.25 (1.19-1.31)	1.00	1.16 (1.10-1.22)

Full statistical model was adjusted for age, sex, chronic kidney disease, hospital, heart failure, prior stroke, COPD, diabetes, prior cardiac revascularization (percutaneous coronary intervention or coronary artery bypass grafts), and use of aspirin, $P2Y_{12}$ inhibitor, beta-blockers, ACE/ARB, and statins the first 6 months following the index date.

Abbreviations as in Tables 1 and 3.

▲表 4 兩個族群接受冠狀動脈攝影及接受冠狀動脈血管重建術的比較

Pharmacodynamic Effects of Switching From Ticagrelor to Clopidogrel in Patients With Coronary Artery Disease (Results of the SWAP-4 Study)

Francesco Franchi, et al.

Circulation. 2018;137:2450–2462.

BACKGROUND

Switching between different classes of $P2Y_{12}$ inhibitors, including de-escalation from ticagrelor to clopidogrel, commonly occurs in clinical practice. However, the pharmacodynamic profiles of this strategy have been poorly explored.

METHODS

This was a prospective, randomized, open-label study conducted in patients on maintenance dosing (MD) of aspirin (81 mg/d) and clopidogrel (75 mg/d). After a 7-day run-in with ticagrelor (180 mg loading dose [LD] followed by 90 mg twice daily MD), patients (n=80) were randomized into 1 of 4 groups: group A, clopidogrel 600 mg LD 24 hours after the last MD of ticagrelor (C-600 mg-24h); group B, clopidogrel 600 mg LD 12 hours after the last MD of ticagrelor (C-600 mg-12h); group C, clopidogrel 75 mg/d MD 24 hours after the last MD of ticagrelor (C-75 mg-24h); and group D, ticagrelor 90 mg twice daily MD (T-90 mg twice daily). MD of the randomized treatment was maintained for 10±3 days. Pharmacodynamic assessments were performed at baseline, after run-in, and at 2, 24, 48, and 72 hours and 10 days with $P2Y_{12}$ reaction units by VerifyNow; platelet reactivity index was assessed by vasodilator-stimulated phosphoprotein; and maximal platelet aggregation was determined by light transmittance aggregometry.

RESULTS

T-90 mg twice daily led to lower platelet reactivity than any clopidogrel regimen using all assays at all time points. $P2Y_{12}$ reaction unit levels were similar between the C-600 mg-24h (group A) and the C-75 mg-24h (group C) (P=0.29), including at 48 hours (primary end point; least mean difference, -6.9; 95% confidence interval, -38.1 to 24.3; P=0.66). $P2Y_{12}$ reaction unit levels were lower with C-600 mg-12h (group B) than with C-75 mg-24h (group C; P=0.024). Maximal platelet aggregation over time was lower with both C-600 mg-24h (group A; P=0.041) and C-600 mg-12h (group B; P=0.028) compared with C-75 mg-24h (group C). Platelet reactivity index profiles paralleled those observed with $P2Y_{12}$ reaction units. There were no pharmacodynamic differences for all tests between C-600 mg-24h (group A) and C-600 mg-12h (group B). In group C (C-75 mg-24h), platelet reactivity increased compared with baseline as early as 24 hours, reaching statistical significance at 48 and 72 hours and up to 10 days. These pharmacodynamic findings were delayed and blunted in magnitude with the administration of an LD, regardless of the timing of administration.

CONCLUSIONS

De-escalation from ticagrelor to clopidogrel therapy is associated with an increase in platelet reactivity. The use of an LD before the initiation of an MD regimen of clopidogrel mitigates these observations, although this is not affected by the timing of its administration after ticagrelor discontinuation.

冠狀動脈疾病患者從 Ticagrelor 轉換成 Clopidogrel 之藥物動力學上影響：SWAP- 4 Study

編譯：臺大醫院 心臟內科 陳翰興醫師

摘要

背景

臨床上常面臨不同 $P2Y_{12}$ 抑制劑之間轉換使用，例如將 Ticagrelor 降階 (de-escalation) 成 Clopidogrel。然而過去沒有探討過這對藥物動力學上的影響，以及藥物之間究竟該如何轉換。

方法

這是一個前瞻性、隨機分派與開放式的研究，納入因冠狀動脈心臟病服用維持劑量 Aspirin(81 mg/d) 和 Clopidogrel(75mg/d) 之受試者。於 7 天的準備期間 (run-in period) 將 clopodogrel 轉換為 Ticagrelor (給予 Ticagrelor 180mg 負荷劑量與 90mg 每日兩次的維持劑量)。之後將受試者 (共計 80 人) 隨機分派成四組。A 組 : 停用 Ticagrelor 24 小時後，給予 Clopidogrel 600mg 負荷劑量 (C-600 mg-24h);；B 組 : 在停用 Ticagrelor 12 小時後給予 Clopidogrel 600mg 負荷劑量 (C-600 mg-12h)；C 組 : 在停用 Ticagrelor 24 小時後，給予 Clopidogrel 每日 75mg 維持劑量 (C-75 mg-24h)；D 組 : 持續使用 Ticagrelor 90mg 每日兩次的維持劑量 (T-90 mg twice daily)。四組的維持劑量都持續再給予 10±3 天。

藥物動力學於基準點 (baseline)，準備期後 (after run-in)0、2、24、48、72 小時，還有 10 天進行檢測。檢測方式採用 $P2Y_{12}$ 接受器檢測試劑組 (VerifyNow $P2Y_{12}$ assay) 來測量 $P2Y_{12}$ 反應單位 ($P2Y_{12}$ reaction units, PRU)、使用血小板血管舒張劑刺激磷蛋白 (vasodilator stimulated phosphoprotein, VASP) 磷酸化水平來判斷血小板反應活性指數 (platelet reactivity index, PRI)，以及使用光學凝集測量儀 (light transmittance Aggregation, LTA) 來評估血小板最大聚集率 (maximal platelet aggregation)。

結果

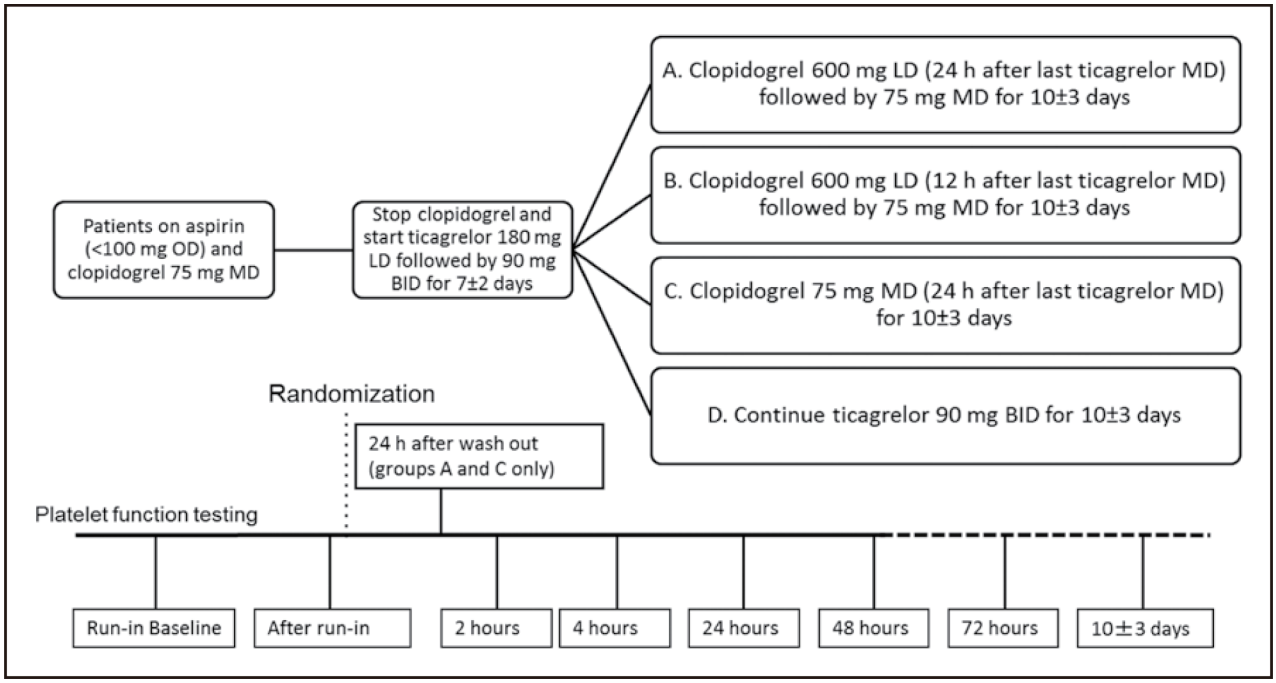
跟其他有轉換使用 Clopidogrel 的組別比起來，D 組 (T-90 mg twice daily) 用各種檢驗方法皆顯示在任何時間點都有較低的血小板活性。而 A 組與 C 組在 $P2Y_{12}$ 反應單位 (PRU) 結果無顯著差異 (p=0.29)。B 組與 C 組相比，有較低的 PRU(p=0.024)。至於血小板最大聚集率 (maximal platelet aggregation)，A、B 兩組皆比 C 組還要低。而血小板反應活性指數 (platelet reactivity index) 的部分，則和 PRU 做出來的結果一致。在 A、B 組之間，各種檢驗顯示無藥物動力學上的差異。在 C 組，血小板的活性早在 24 小時候和基準點相比就顯示有顯著升高，而在 48 小時、72 小時及 10 天後的檢驗結果亦然。若是在有給負荷劑量的 A 與 B 組，血小板活性和基準點相比依然會升高，只是活性強度的差別會較小且時間上會較晚出現，但 A 與 B 組之間並沒有差異。

結論

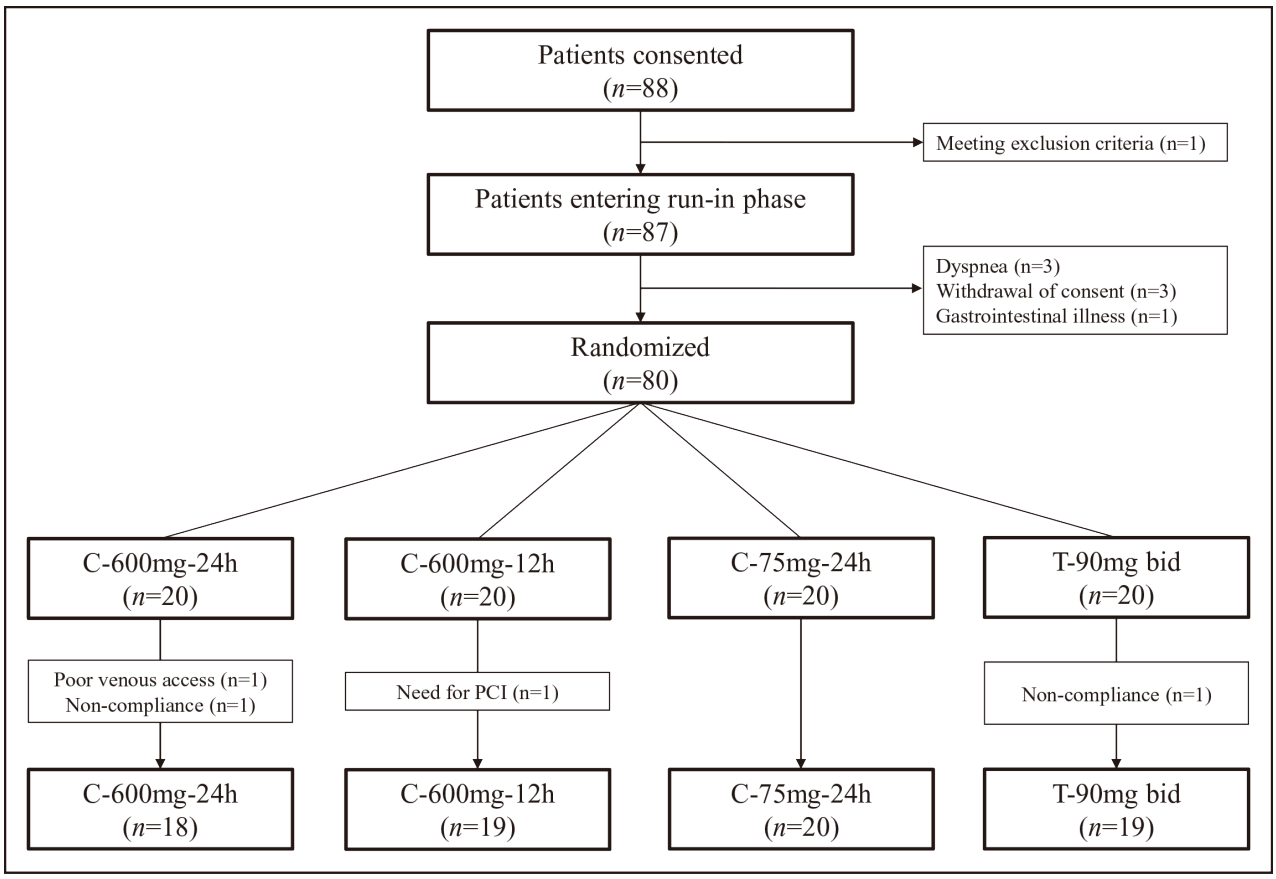
從 Ticagrelor 降階到 Clopidogrel 會造成血小板活性的增加。在使用 Clopidogrel 維持劑量前給予負荷劑量會減緩這個現象，但要何時給予負荷劑量 (停 Ticagrelor 後 12 小時或 24 小時) 並沒有差別。

臨床應用

1. 如果臨床需要使用到 $P2Y_{12}$ 抑制劑的降階治療，特別是從 Ticagrelor 轉換成 Clopidogrel，應考慮給予 Clopidogrel 600mg 負荷劑量，除非病人是因為出血而不得不降階治療。
2. Clopidogrel 負荷劑量可依臨床狀況於最合適的時候給予 (停用 Ticagrelor 後 12 或 24 小時)



▲圖 1 研究設計

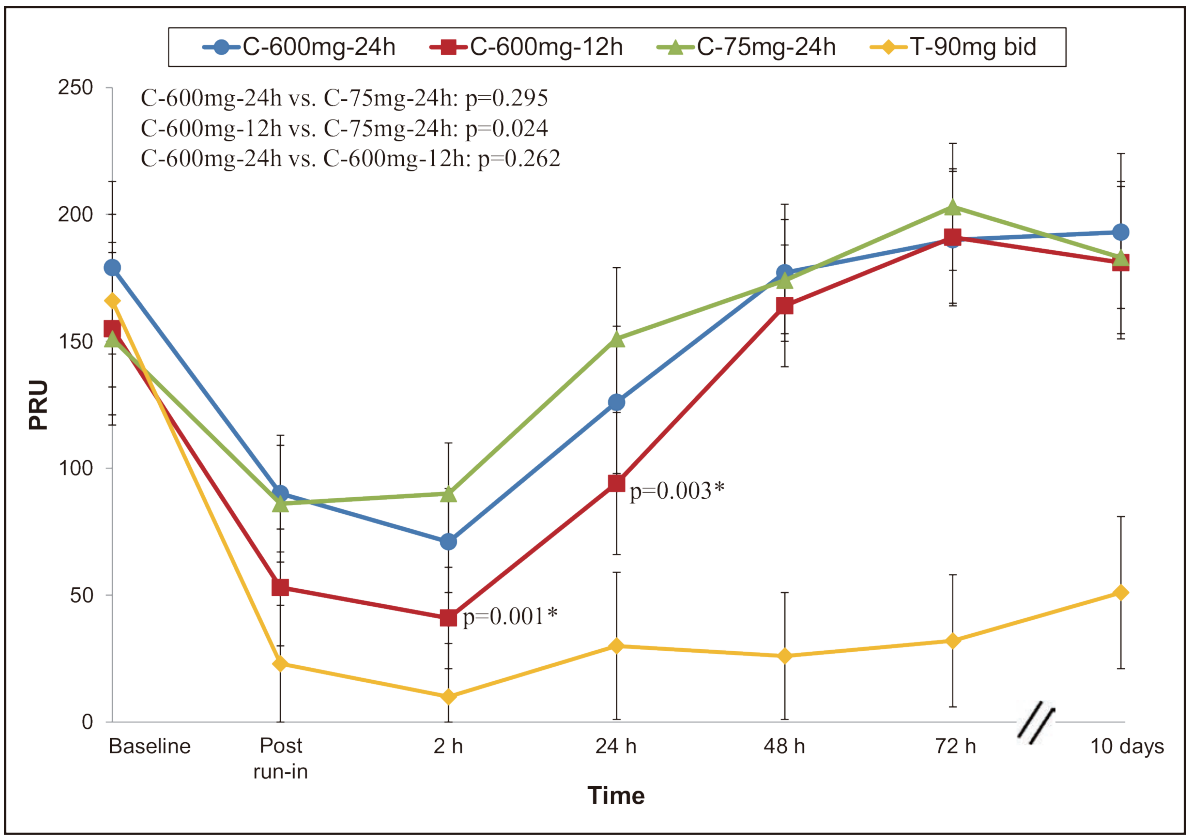


▲圖 2 病人分組

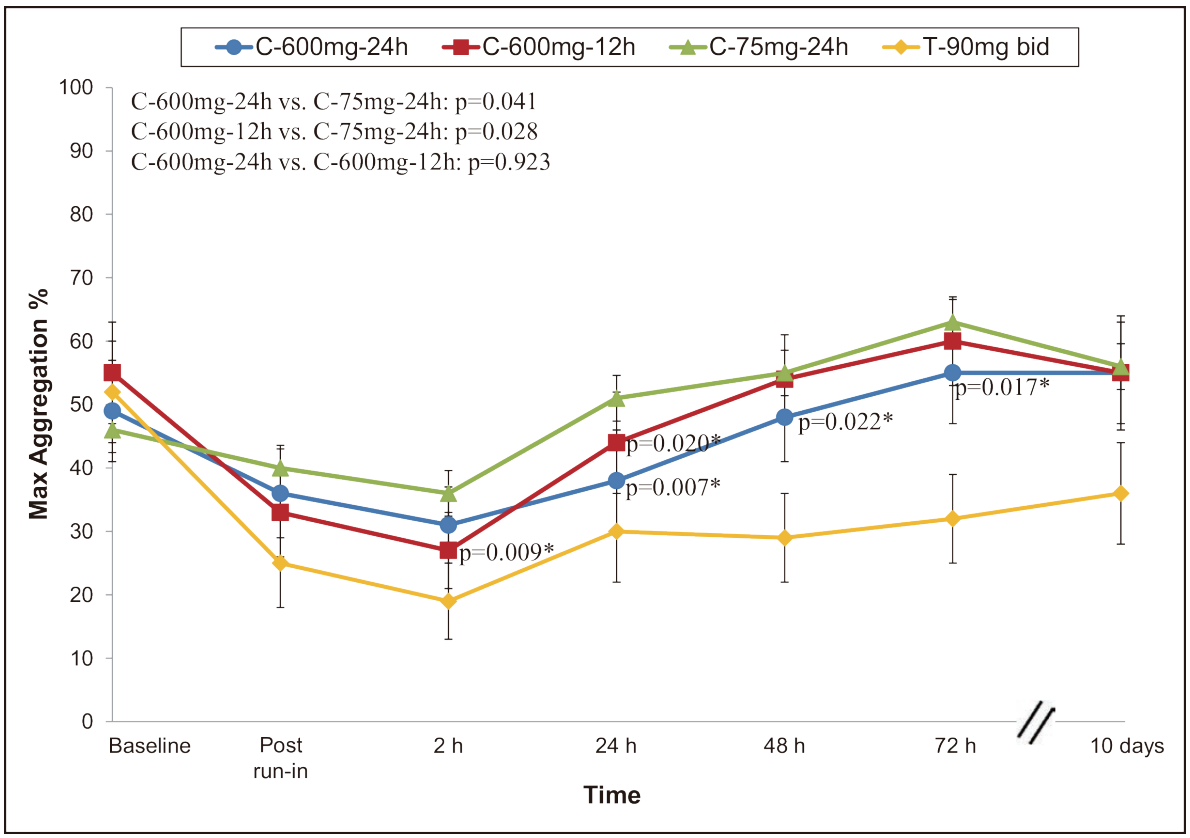
Table 1. Baseline Characteristics of the Pharmacodynamic Population

Characteristics	C-600 mg-24h (n=20)	C-600 mg-12h (n=20)	C-75 mg-24h (n=20)	T-90 mg BID (n=20)	*P* Value
Age, y	62±7	65±8	63±9	58±9	0.09
Men, n (%)	11 (55)	15 (75)	13 (65)	12 (60)	0.59
BMI, kg/m^2	32±8	31±4	31±5	31±9	0.86
Race, n (%)					0.44
White	10 (50)	14 (70)	13 (65)	14 (70)	
Black	10 (50)	5 (25)	7 (35)	6 (30)	
Other	0 (0)	1 (5)	0 (0)	0 (0)	
Diabetes mellitus, n (%)	9 (45)	9 (45)	6 (30)	5 (25)	0.43
CKD, n (%)	3 (15)	2 (10)	0 (0)	1 (5)	0.31
Hypertension, n (%)	15 (75)	19 (95)	15 (75)	14 (70)	0.26
Dyslipidemia, n (%)	18 (90)	19 (95)	17 (85)	17 (85)	0.71
Smoking, n (%)	7 (35)	6 (30)	5 (25)	7 (35)	0.29
PAD, n (%)	4 (20)	3 (15)	3 (15)	3 (15)	0.97
Prior stroke, n (%)	6 (30)	1 (5)	4 (20)	3 (15)	0.21
Prior MI, n (%)	11 (55)	11 (55)	15 (75)	14 (70)	0.43
Prior PCI, n (%)	20 (100)	17 (85)	18 (90)	20 (100)	0.12
Prior CABG, n (%)	5 (25)	5 (25)	9 (45)	5 (25)	0.41
LOF allele, n (%)	6 (30)	0 (0)	5 (25)	7 (35)	0.04
Heterozygous	6 (30)	0 (0)	4 (20)	7 (35)	
Homozygous	0 (0)	0 (0)	1 (5)	0 (0)	
GOF allele, n (%)	0 (0)	1 (5)	0 (0)	2 (10)	0.89
Medications, n (%)					
OAD	3 (15)	7 (35)	2 (10)	4 (20)	0.22
Insulin	5 (25)	5 (25)	3 (15)	2 (10)	0.53
β-Blockers	15 (75)	17 (85)	19 (95)	16 (80)	0.36
ACEi/ARB	12 (60)	13 (65)	14 (70)	13 (65)	0.93
Statins	20 (100)	20 (100)	20 (100)	20 (100)	1
PPI*	5 (25)	4 (20)	5 (25)	4 (20)	0.96
Hemoglobin, g/dL	13.1±1.3	13.3±1.3	13.8±1.8	13.7±1.8	0.43
Creatinine, mg/dL	1.1±0.3	1.0±0.2	1.0±0.3	0.9±0.2	0.26
CrCl, mL/min	96±37	96±28	101±44	109±41	0.69
Hematocrit, %	39±4	40±3	42±5	41±4	0.32
Platelet count, 1000/mm^3	196±74	223±54	248±87	243±57	0.09

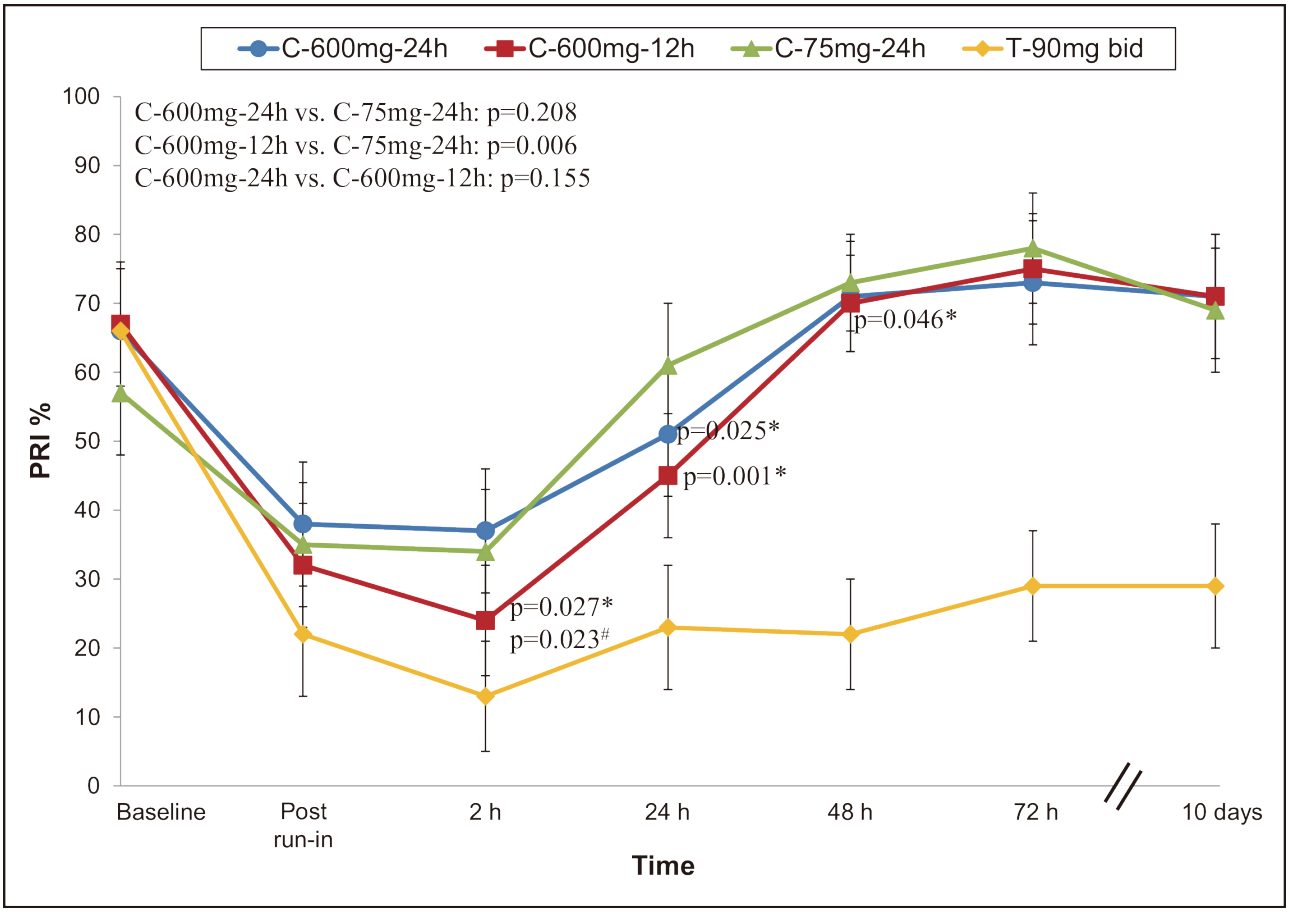
▲表 1 各組基本資料



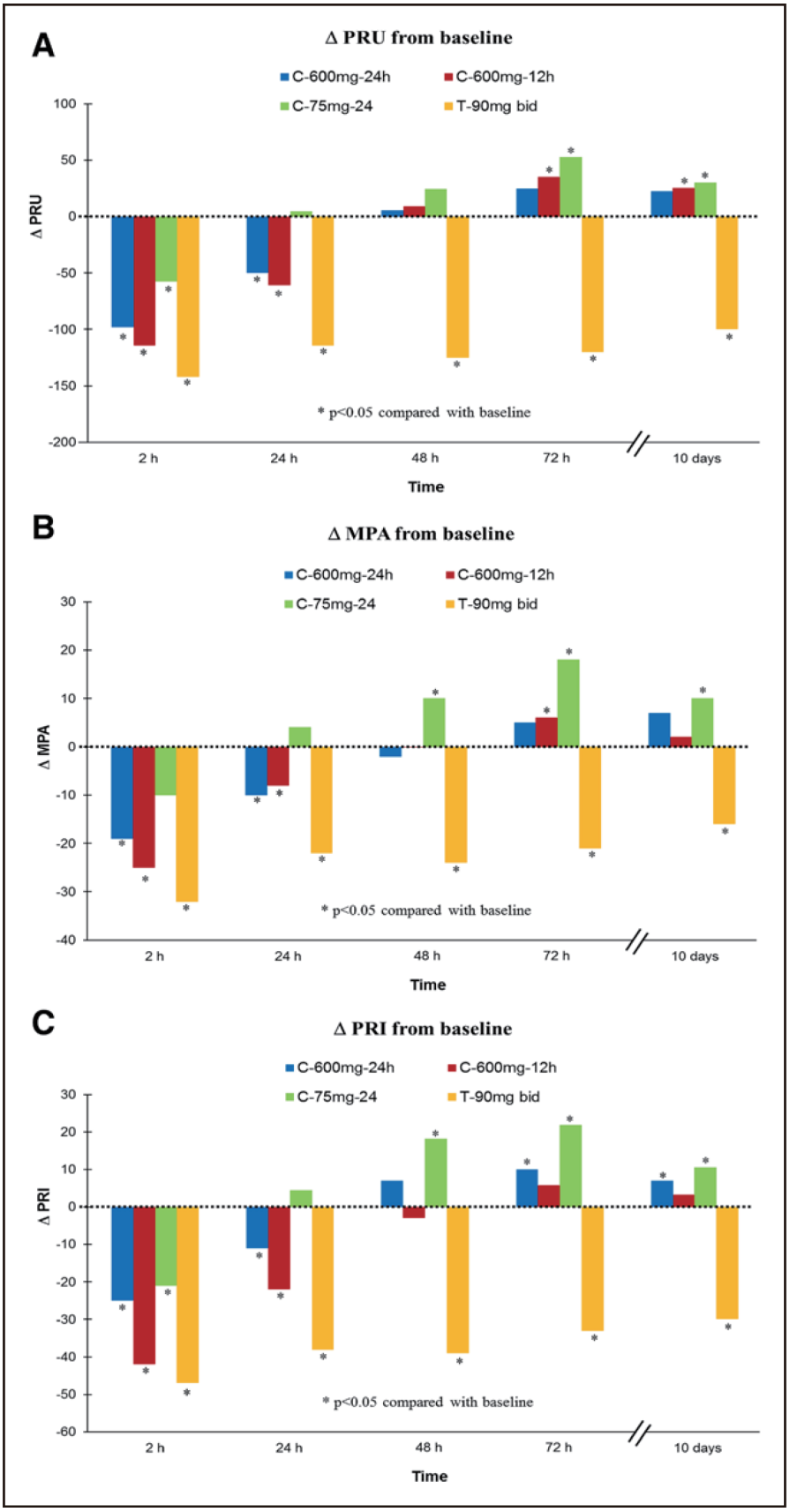
▲圖 3 各組 $P2Y_{12}$ 反應單位 ($P2Y_{12}$ reaction units, PRU) 的曲線圖



▲圖 4 各組血小板最大聚集率 (maximal platelet aggregation) 的曲線圖



▲圖 5 各組血小板反應的活性指數 (platelet reactivity index，PRI) 的曲線圖



▲圖 6 各組在不同時間點血小板活性的變化

Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging

Albers GW, et al.

N Engl J Med. 2018 Feb 22;378(8):708-718

BACKGROUND

Thrombectomy is currently recommended for eligible patients with stroke who are treated within 6 hours after the onset of symptoms.

METHODS

We conducted a multicenter, randomized, open-label trial, with blinded outcome assessment, of thrombectomy in patients 6 to 16 hours after they were last known to be well and who had remaining ischemic brain tissue that was not yet infarcted. Patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion, an initial infarct size of less than 70 ml, and a ratio of the volume of ischemic tissue on perfusion imaging to infarct volume of 1.8 or more were randomly assigned to endovascular therapy (thrombectomy) plus standard medical therapy (endovascular-therapy group) or standard medical therapy alone (medical-therapy group). The primary outcome was the ordinal score on the modified Rankin scale (range, 0 to 6, with higher scores indicating greater disability) at day 90.

RESULTS

The trial was conducted at 38 U.S. centers and terminated early for efficacy after 182 patients had undergone randomization (92 to the endovascular-therapy group and 90 to the medical-therapy group). Endovascular therapy plus medical therapy, as compared with medical therapy alone, was associated with a favorable shift in the distribution of functional outcomes on the modified Rankin scale at 90 days (odds ratio, 2.77; P<0.001) and a higher percentage of patients who were functionally independent, defined as a score on the modified Rankin scale of 0 to 2 (45% vs. 17%, P<0.001). The 90-day mortality rate was 14% in the endovascular-therapy group and 26% in the medical-therapy group (P=0.05), and there was no significant between-group difference in the frequency of symptomatic intracranial hemorrhage (7% and 4%, respectively; P=0.75) or of serious adverse events (43% and 53%, respectively; P=0.18).

CONCLUSIONS

Endovascular thrombectomy for ischemic stroke 6 to 16 hours after a patient was last known to be well plus standard medical therapy resulted in better functional outcomes than standard medical therapy alone among patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion and a region of tissue that was ischemic but not yet infarcted. (Funded by the National Institute of Neurological Disorders and Stroke; DEFUSE 3 ClinicalTrials.gov number, NCT02586415 .)

透過腦灌流影像選擇性在急性中風後 6-16 小時使用血栓移除術

編譯：臺大醫院 心臟內科 劉彥廷醫師

背景

血栓移除術 (thrombectomy) 目前建議運用於急性中風症狀發生 6 小時內且符合相關條件之病人。

方法

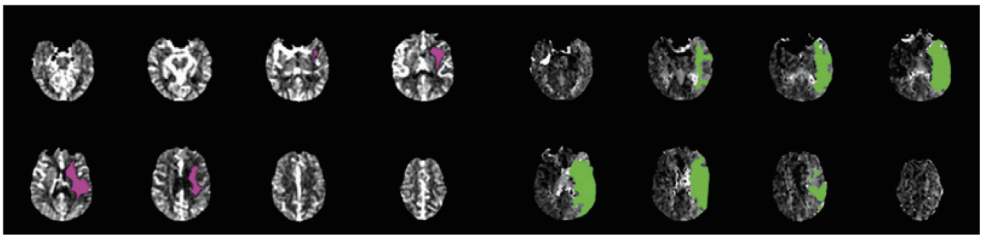
本研究為多中心、隨機分派與開放式臨床試驗，盲性結果評估 (blinded outcome assessment) 血栓移除術對於急性中風症狀發生後 6 到 16 小時，仍有缺血而非梗塞腦組織的臨床療效。同時符合包括近端中大腦動脈或內頸動脈阻塞、初始梗塞容積 < 70 ml 與腦灌流影像 (perfusion imaging) 缺血容積為梗塞容積的 1.8 倍以上與預估 pneumbra 超過 15ml 以上等條件之病人，隨機分派到 endovascular-therapy group (血栓移除術合併標準藥物治療) 或 medical-therapy group (僅接受標準藥物治療)。所有病人於中風 4.5 小時內可給予 intravenous tPA (tissue plasminogen activator)，但均不能使用 IA tPA (不過最終有 2 位 endovascular-therapy group 病人接受 IA tPA)。主要試驗評估是第 90 天的 modified Rankin scale。

結果

本試驗在美國 38 個醫學中心進行，試驗因臨床療效提前結案。共計 182 位受試者，其中 92 人為 endovascular-therapy group，90 人為 medical-therapy group。相較於標準藥物治療，血栓移除術合併標準藥物治療可改善第 90 天的 modified Rankin scale 之分布 (odds ratio, 2.77; P < 0.001)，且有較高比例的病人為神經功能恢復較佳，modified Rankin scale 介於 0~2 分 (45% vs. 17%, P < 0.001)。90 天內死亡率在 endovascular-therapy group 及 medical-therapy group 分別為 26% 及 14% (P = 0.05)，且兩組間發生有症狀之顱內出血 (7% vs 4%, P = 0.75) 或嚴重不良反應 (43% vs. 53%, P = 0.18) 之比例均無顯著差異。

結論

血栓移除術合併標準藥物治療於缺血性中風發生後 6 到 16 小時內，梗塞部位為近端中大腦動脈或內頸動脈阻塞，且仍有缺血而非梗塞的腦組織的病人，相較於單獨標準藥物治療，可顯著改善神經功能。



Volume of Ischemic Core, 23 ml

Volume of Perfusion Lesion, 128 ml

Mismatch volume, 105 ml
Mismatch ratio, 5.6

Figure 1. Example of Perfusion Imaging Showing a Disproportionately Large Region of Hypoperfusion as Compared with the Size of Early Infarction.

A 59-year-old man presented with a "wake-up stroke" (having awakened with symptoms of stroke) 13 hours after he was last known to be well. The score on the National Institutes of Health Stroke Scale (NIHSS; range, 0 to 42, with higher scores indicating a greater deficit) was 23. A baseline CT perfusion scan that was obtained with the use of RAPID software shows a region of severely reduced cerebral blood flow (<30% of that in normal tissue), which represents the early infarct (ischemic core), of 23 ml (pink) and a region of perfusion delay of more than 6 seconds, which represents hypoperfused tissue, of 128 ml (green).

▲圖一 腦灌流影像範例

Table 1. Baseline Characteristics of the Patients and Features of Thrombectomy.*

Characteristic	Endovascular Therapy (N = 92)	Medical Therapy (N = 90)
Median age (IQR) — yr	70 (59–79)	71 (59–80)
Female sex — no. (%)	46 (50)	46 (51)
Median NIHSS score (IQR)†	16 (10–20)	16 (12–21)
Stroke onset witnessed — no. (%)		
Yes‡	31 (34)	35 (39)
No		
Symptoms were present on awakening	49 (53)	42 (47)
Symptoms began during wakefulness	12 (13)	13 (14)
Treatment with intravenous t-PA — no. (%)§	10 (11)	8 (9)
Imaging characteristics¶		
Qualifying imaging — no. (%)		
CT perfusion imaging	69 (75)	64 (71)
Diffusion and perfusion MRI	23 (25)	26 (29)
Median volume of ischemic core (IQR) — ml	9.4 (2.3–25.6)	10.1 (2.1–24.3)
Median volume of perfusion lesion (IQR) — ml‖	114.7 (79.3–146.3)	116.1 (73.4–158.2)
Occlusion site on baseline CTA or MRA — no. (%)		
Internal carotid artery	32 (35)	36 (40)
Middle cerebral artery**	60 (65)	54 (60)
Median ASPECTS on baseline CT (IQR)††	8 (7–9)	8 (7–9)
Process measures — hr:min		
Median time from stroke onset to qualifying imaging (IQR)	10:29 (8:09–11:40)	9:55 (7:59–12:20)
Median time from stroke onset to randomization (IQR)	10:53 (8:46–12:21)	10:44 (8:42–13:04)
Median time from qualifying imaging to femoral puncture (IQR)	0:59 (0:39–1:27)	NA
Median time from femoral puncture to reperfusion (IQR)	0:38 (0:26- 0:59)	NA

▲表一 病人基本資料

註：所有中大腦動脈阻塞皆有侵犯到 M1，僅 1 位 medical-therapy group 的病人有侵犯到 M2

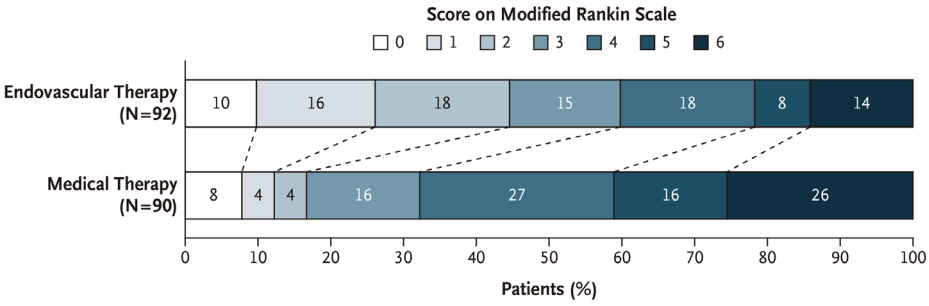


Figure 2. Scores on the Modified Rankin Scale at 90 Days.

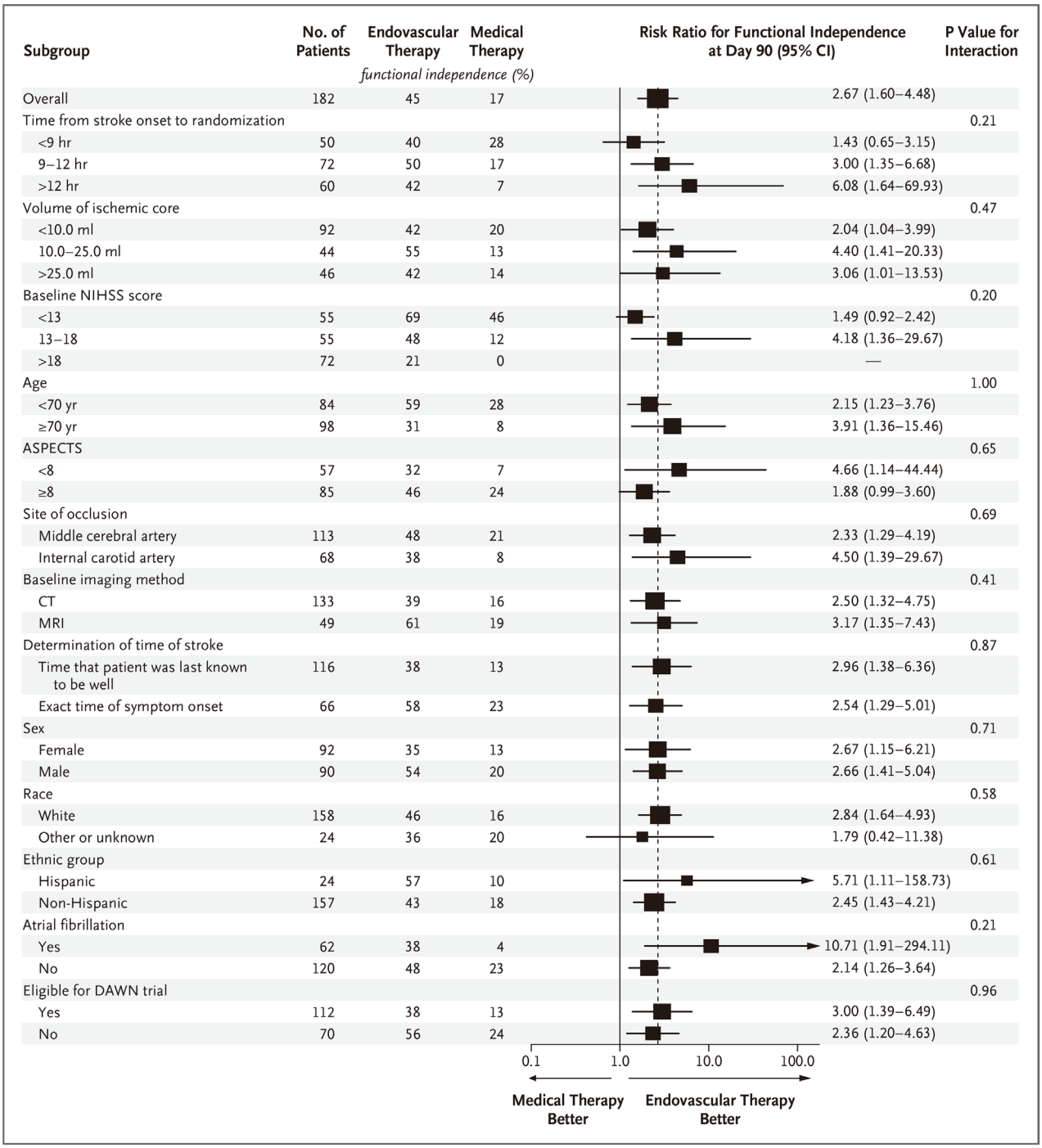
Patients in the endovascular-therapy group received endovascular therapy plus standard medical therapy. Patients in the medical-therapy group received standard medical therapy alone. Scores on the modified Rankin scale range from 0 to 6, with 0 indicating no symptoms, 1 no clinically significant disability, 2 slight disability, 3 moderate disability, 4 moderately severe disability, 5 severe disability, and 6 death. There was a significant difference favoring the endovascular-therapy group over the medical-therapy group in the overall distribution of scores (unadjusted common odds ratio, 2.77; 95% CI, 1.63 to 4.70; P<0.001).

▲圖二 第 90 天的 modified Rankin scale

Table 2. Clinical and Imaging Outcomes.

Outcome	Endovascular Therapy (N = 92)*	Medical Therapy (N = 90)	Odds Ratio or Risk Ratio (95% CI)†	P Value
Primary efficacy outcome: median score on modified Rankin scale at 90 days (IQR)‡	3 (1–4)	4 (3–6)	2.77 (1.63–4.70)§	<0.001
Secondary efficacy outcome: functional independence at 90 days — no. (%)¶	41 (45)	15 (17)	2.67 (1.60–4.48)	<0.001
Safety outcomes — no. (%)				
Death at 90 days	13 (14)	23 (26)	0.55 (0.30–1.02)	0.05
Symptomatic intracranial hemorrhage‖	6 (7)	4 (4)	1.47 (0.40–6.55)	0.75
Early neurologic deterioration	8 (9)	11 (12)	0.71 (0.30–1.69)	0.44
Parenchymal hematoma type 2	8 (9)	3 (3)	2.61 (0.73–14.69)	0.21
Imaging outcomes**				
Median infarct volume at 24 hr (IQR) — ml	35 (18–82)	41 (25–106)	—	0.19
Median infarct growth at 24 hr (IQR) — ml	23 (10–75)	33 (18–75)	—	0.08
Reperfusion >90% at 24 hr — no./total no. (%)	59/75 (79)	12/67 (18)	4.39 (2.60–7.43)	<0.001
Complete recanalization at 24 hr — no./total no. (%)	65/83 (78)	14/77 (18)	4.31 (2.65–7.01)	<0.001
TICI score of 2b or 3 — no./total no. (%)	69/91 (76)	—	—	

▲表二 臨床及影像學之終點



Subgroup	No. of Patients	Endovascular Therapy	Medical Therapy	Risk Ratio for Functional Independence at Day 90 (95% CI)	P Value for Interaction
		functional independence (%)			
Overall	182	45	17	2.67 (1.60–4.48)	
Time from stroke onset to randomization					0.21
<9 hr	50	40	28	1.43 (0.65–3.15)	
9–12 hr	72	50	17	3.00 (1.35–6.68)	
>12 hr	60	42	7	6.08 (1.64–69.93)	
Volume of ischemic core					0.47
<10.0 ml	92	42	20	2.04 (1.04–3.99)	
10.0–25.0 ml	44	55	13	4.40 (1.41–20.33)	
>25.0 ml	46	42	14	3.06 (1.01–13.53)	
Baseline NIHSS score					0.20
<13	55	69	46	1.49 (0.92–2.42)	
13–18	55	48	12	4.18 (1.36–29.67)	
>18	72	21	0	—	
Age					1.00
<70 yr	84	59	28	2.15 (1.23–3.76)	
≥70 yr	98	31	8	3.91 (1.36–15.46)	
ASPECTS					0.65
<8	57	32	7	4.66 (1.14–44.44)	
≥8	85	46	24	1.88 (0.99–3.60)	
Site of occlusion					0.69
Middle cerebral artery	113	48	21	2.33 (1.29–4.19)	
Internal carotid artery	68	38	8	4.50 (1.39–29.67)	
Baseline imaging method					0.41
CT	133	39	16	2.50 (1.32–4.75)	
MRI	49	61	19	3.17 (1.35–7.43)	
Determination of time of stroke					0.87
Time that patient was last known to be well	116	38	13	2.96 (1.38–6.36)	
Exact time of symptom onset	66	58	23	2.54 (1.29–5.01)	
Sex					0.71
Female	92	35	13	2.67 (1.15–6.21)	
Male	90	54	20	2.66 (1.41–5.04)	
Race					0.58
White	158	46	16	2.84 (1.64–4.93)	
Other or unknown	24	36	20	1.79 (0.42–11.38)	
Ethnic group					0.61
Hispanic	24	57	10	5.71 (1.11–158.73)	
Non-Hispanic	157	43	18	2.45 (1.43–4.21)	
Atrial fibrillation					0.21
Yes	62	38	4	10.71 (1.91–294.11)	
No	120	48	23	2.14 (1.26–3.64)	
Eligible for DAWN trial					0.96
Yes	112	38	13	3.00 (1.39–6.49)	
No	70	56	24	2.36 (1.20–4.63)	

▲圖三 次群組分析 (subgroup analyses)

3.7. Mechanical Thrombectomy (Continued)	COR	LOE	New, Revised, or Unchanged
7. In selected patients with AIS within 6 to 16 hours of last known normal who have LVO in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria, mechanical thrombectomy is recommended.	I	A	New recommendation.
8. In selected patients with AIS within 6 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable.	IIa	B-R	New recommendation.

▲表三 2018年美國急性缺血性中風指引之更新 (Stroke 2018;49:e46-e110)

Endovascular ultrasound renal denervation to treat hypertension (RADIANCE-HTN SOLO): a multicentre, international, single-blind, randomised, sham-controlled trial

Azizi M et al.

Lancet. 2018 Jun 9;391(10137):2335-2345.

BACKGROUND

Early studies suggest that radiofrequency-based renal denervation reduces blood pressure in patients with moderate hypertension. We investigated whether an alternative technology using endovascular ultrasound renal denervation reduces ambulatory blood pressure in patients with hypertension in the absence of antihypertensive medications.

Methods

RADIANCE-HTN SOLO was a multicentre, international, single-blind, randomised, sham-controlled trial done at 21 centres in the USA and 18 in Europe. Patients with combined systolic–diastolic hypertension aged 18-75 years were eligible if they had ambulatory blood pressure greater than or equal to 135/85 mm Hg and less than 170/105 mm Hg after a 4-week discontinuation of up to two antihypertensive medications and had suitable renal artery anatomy. Patients were randomised (1:1) to undergo renal denervation with the Paradise system (ReCor Medical, Palo Alto, CA, USA) or a sham procedure consisting of renal angiography only. The randomisation sequence was computer generated and stratifed by centres with randomised blocks of four or six and permutation of treatments within each block. Patients and outcome assessors were blinded to randomisation. The primary effectiveness endpoint was the change in daytime ambulatory systolic blood pressure at 2 months in the intention-to-treat population. Patients were to remain off antihypertensive medications throughout the 2 months of follow-up unless specifed blood pressure criteria were exceeded. Major adverse events included all-cause mortality, renal failure, an embolic event with end-organ damage, renal artery or other major vascular complications requiring intervention, or admission to hospital for hypertensive crisis within 30 days and new renal artery stenosis within 6 months. This study is registered with ClinicalTrials.gov, number NCT02649426

Findings

Between March 28, 2016, and Dec 28, 2017, 803 patients were screened for eligibility and 146 were randomised to undergo renal denervation (n=74) or a sham procedure (n=72). The reduction in daytime ambulatory systolic blood pressure was greater with renal denervation (–8·5 mm Hg, SD 9·3) than with the sham procedure (–2·2 mm Hg, SD 10·0; baseline-adjusted difference between groups: –6·3 mm Hg, 95% CI –9·4 to –3·1, p=0·0001). No major adverse events were reported in either group.

Interpretation

Compared with a sham procedure, endovascular ultrasound renal denervation reduced ambulatory blood pressure at 2 months in patients with combined systolic–diastolic hypertension in the absence of medications.

利用血管內超音波腎動脈神經阻斷術治療高血壓 (RADIANCE-HTN SOLO): 多中心跨國單盲隨機合併安慰劑手術臨床試驗

編譯：臺大醫院 心臟內科 潘建廷醫師

背景

先前的臨床試驗顯示射頻燒灼腎動脈神經阻斷術能對於中度高血壓患者有降低血壓的效果。而本研究目的為評估新技術血管內超音波腎動脈神經阻斷術是否能在未使用降血壓藥物的高血壓患者達到降低血壓的效果。

方法

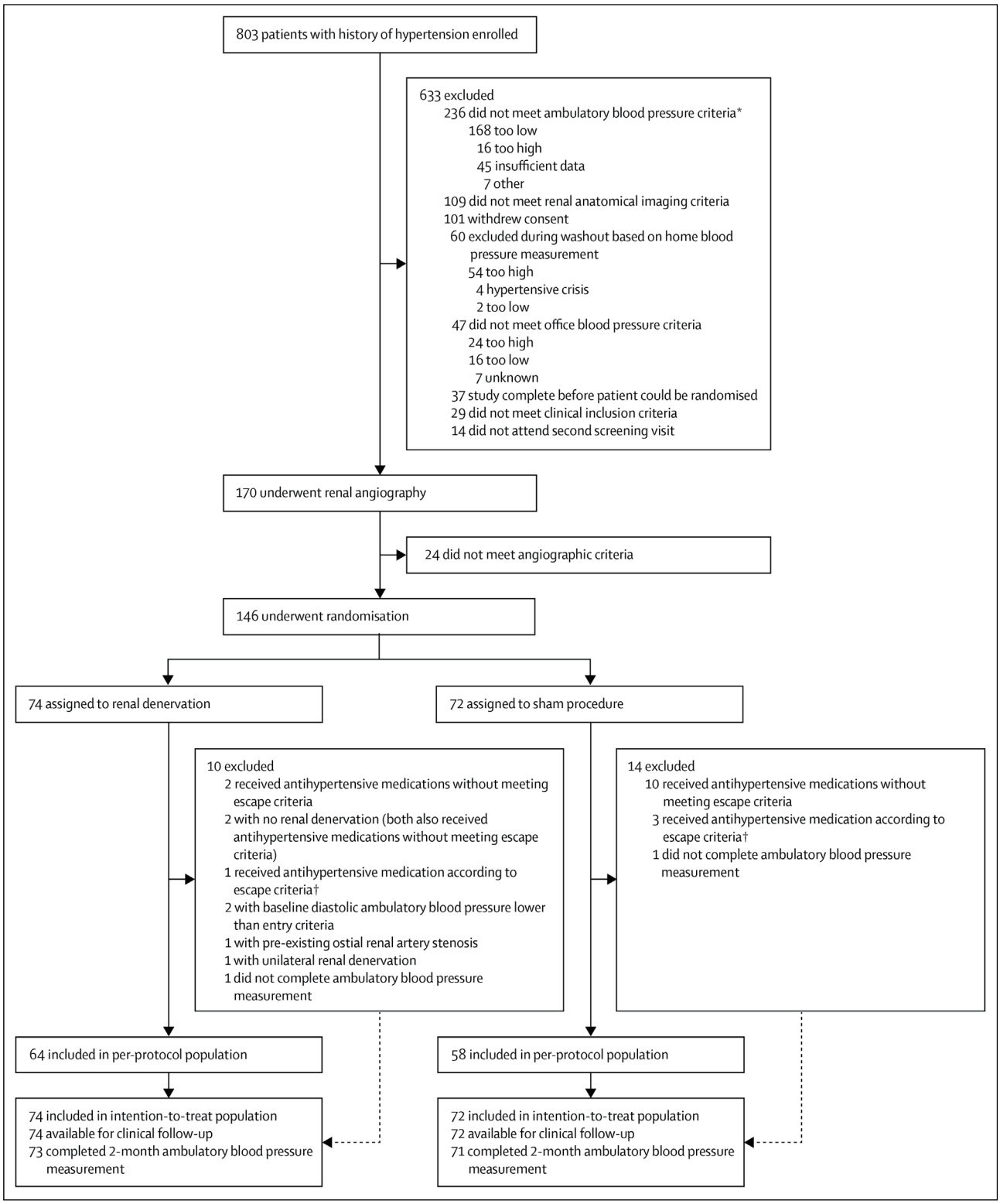
RADIANCE-HTN SOLO 是一項多中心、跨國、單盲、隨機分派合併安慰劑手術的臨床試驗，參與機構有 21 處位於美國 18 處位於歐洲。高血壓患者納入條件為年齡 18~75 歲之間、停用降血壓藥四週後活動式血壓量測，血壓 ≥ 135/85 毫米汞柱及小於 170/105 毫米汞柱，同時經評估有可執行手術的腎動脈解剖構造。受試者經隨機分派分成實驗組，使用 Paradise system (ReCor Medical, Palo Alto, CA, USA) 進行血管內超音波腎動脈神經阻斷術；與對照組，施行單純腎動脈血管造影的安慰劑手術。透過電腦隨機分派，受試者及臨床結果分析者都會被隨機且不會被告知分組結果。這項臨床試驗的主要療效評估為在意向治療分析 (intention-to-treat analysis) 之下分組治療兩個月後的平日活動式血壓量測改變；在隨機分配接受治療之後兩個月內除非血壓達到特定的異常狀況，受試者將不會重啟降血壓藥物治療。嚴重不良事件包括全因死亡率、腎臟衰竭、血栓事件造成器官衰竭、腎動脈或是其他需要接受治療的嚴重的血管併發症，30 天內高血壓危象入院或是 6 個月內新發生腎動脈狹窄。

結果

在收案期間 2016 年 3 月至 2017 年 12 月，有 803 名患者被納入試驗篩選而最終有 146 名患者進入臨床試驗中進行分組，而當中有 74 名患者接受血管內超音波腎動脈神經阻斷術，有 72 名患者接受安慰劑手術。在接受血管內超音波腎動脈神經阻斷術實驗組中，患者被發現手術能夠降低平日活動式血壓量測的收縮壓達 8.5 毫米汞柱，相比於安慰劑手術的對照組的下降 2.2 毫米汞柱，有達到顯著差異的 6.3 毫米汞柱的差別 (p=0.0001)。在試驗的兩個組別內都沒有嚴重不良事件的發生。

結論

與對照組的安慰劑手術相比，於收縮壓與舒張壓皆升高且沒有使用降血壓藥物治療之患者，血管內超音波腎動脈神經阻斷術能夠有效地降低術後 2 個月的收縮壓。



▲圖一 臨床試驗收案及設計

	Renal denervation (n=74)	Sham procedure (n=72)
Age (years)	54·4 (10·2)	53·8 (10·0)
Female sex	28 (38%)	33 (46%)
Race		
White	60 (81%)	52 (72%)
Black	12 (16%)	13 (18%)
Other	2 (3%)	7 (10%)
Body-mass index (kg/m²)	29·9 (5·9)	29·0 (5·0)
Abdominal obesity*	41 (56%)	44 (61%)
eGFR (mL/min per 1·73 m²)	84·7 (16·2)	83·2 (16·1)
eGFR <60 mL/min per 1·73 m²*	1 (1%)	3 (4%)
Diabetes		
Type 1	0	0
Type 2	2 (3%)	5 (7%)
Obstructive sleep apnoea*	6 (8%)	8 (11%)
Office systolic blood pressure before antihypertensive medication washout (mm Hg)	142·6 (14·7)	144·6 (15·9)
Office diastolic blood pressure before antihypertensive medication washout (mm Hg)	92·3 (10·1)	93·6 (8·3)
Office heart rate before antihypertensive medication washout (bpm)	72·0 (12·1)	72·6 (12·3)
Number of antihypertensive medications at screening		
0†	12 (16%)	16 (22%)
1	33 (45%)	28 (39%)
2	28 (38%)	27 (38%)
3‡	1 (1%)	1 (1%)
Types of medication at screening in patients on medications		
Renin angiotensin system blockers		
Angiotensin converting enzyme inhibitor	29 (47%)	28 (50%)
Angiotensin receptor blocker	13 (21%)	13 (23%)
Direct renin inhibitor	2 (3%)	0
Calcium channel blocker	20 (32%)	21 (38%)
Diuretic	9 (15%)	5 (9%)
Beta blocker	5 (8%)	7 (13%)
Alpha-1 receptor blocker	3 (5%)	1 (2%)
Spironolactone	0	1 (2%)

Data are n (%) or mean (SD). eGFR=estimated glomerular filtration rate. bpm=beats per minute. *Abdominal obesity status not available in one patient in renal denervation group, eGFR data were unavailable in one patient in the renal denervation group and three patients in the sham group, and sleep apnoea status was unavailable in one patient in the sham group. †Nine patients were drug naive in the renal denervation (three patients) and sham (six patients) groups and 19 were drug intolerant or had chosen not to take antihypertensive medications (nine in the renal denervation group and ten in the sham group). ‡Two patients were discovered to have been on three antihypertensive medications at screening.

Table 1: **Baseline demographic and clinical characteristics of the intention-to-treat population**

▲表一 組別患者因子分析

	Renal denervation			Sham procedure			Mean between-group difference adjusted for baseline blood pressure (95% CI)	p value
	Randomisation	2 months	Difference	Randomisation	2 months	Difference		
Daytime ambulatory blood pressure (mm Hg)								
Patients with data	74	74	74	72	72	72	..	..
Systolic blood pressure	150·3 (7·8)	141·9 (11·9)	−8·5 (9·3)	150·0 (9·8)	147·9 (13·3)	−2·2 (10·0)	−6·3 (−9·4 to −3·1)	0·0001
Diastolic blood pressure	93·1 (4·8)	87·9 (7·1)	−5·1 (5·9)	93·5 (5·5)	90·9 (7·9)	−2·6 (6·5)	−2·6 (−4·6 to −0·6)	0·01 (0·006*)
24-h ambulatory blood pressure (mm Hg)								
Patients with data	74	74	74	72	72	72	..	..
Systolic blood pressure	142·6 (8·1)	135·6 (11·4)	−7·0 (8·6)	143·8 (10·4)	140·7 (11·8)	−3·1 (9·7)	−4·1 (−7·1 to −1·2)	0·006
Diastolic blood pressure	87·3 (5·0)	83·0 (6·8)	−4·4 (5·8)	88·6 (5·7)	85·7 (7·1)	−3·0 (6·1)	−1·8 (−3·7 to 0·2)	0·07
Night-time ambulatory blood pressure (mm Hg)								
Patients with data	74	74	74	71	71	71	..	..
Systolic blood pressure	130·3 (11·9)	125·6 (12·8)	−4·8 (11·7)	132·5 (13·7)	129·4 (13·1)	−3·1 (11·5)	−2·5 (−6·0 to 0·9)	0·15
Diastolic blood pressure	78·2 (8·0)	74·8 (8·5)	−3·3 (8·5)	80·0 (8·1)	77·3 (8·5)	−2·7 (7·3)	−1·4 (−3·8 to 1·0)	0·25
Office blood pressure (mm Hg)								
Patients with data	74	74	74	72	72	72	..	..
Systolic blood pressure	154·5 (12·4)	143·7 (16·1)	−10·8 (13·6)	153·6 (15·7)	149·7 (17·4)	−3·9 (17·4)	−6·5 (−11·3 to −1·8)	0·007 (0·0007*)
Diastolic blood pressure	99·7 (7·7)	94·2 (10·1)	−5·5 (8·4)	99·1 (9·4)	98·0 (10·0)	−1·2 (10·0)	−4·1 (−7·0 to −1·3)	0·005
Home blood pressure (mm Hg)								
Patients with data	71	71	71	72	72	72	..	..
Systolic blood pressure	147·5 (8·8)	139·4 (11·7)	−8·1 (9·7)	147·7 (12·3)	146·6 (15·4)	−1·1 (10·6)	−7·1 (−10·4 to −3·8)	<0·0001 (<0·0001*)
Diastolic blood pressure	94·8 (6·9)	89·9 (7·8)	−4·9 (6·7)	94·6 (7·0)	93·3 (8·5)	−1·3 (6·2)	−3·6 (−5·6 to −1·5)	0·0009

Data are mean (SD) unless otherwise noted. p values are from analysis of covariance, adjusting for baseline value. *p value by baseline adjusted analysis of covariance on ranked data.

Table 2: **Primary and secondary efficacy endpoints**

▲表二 主要及次要療效終點

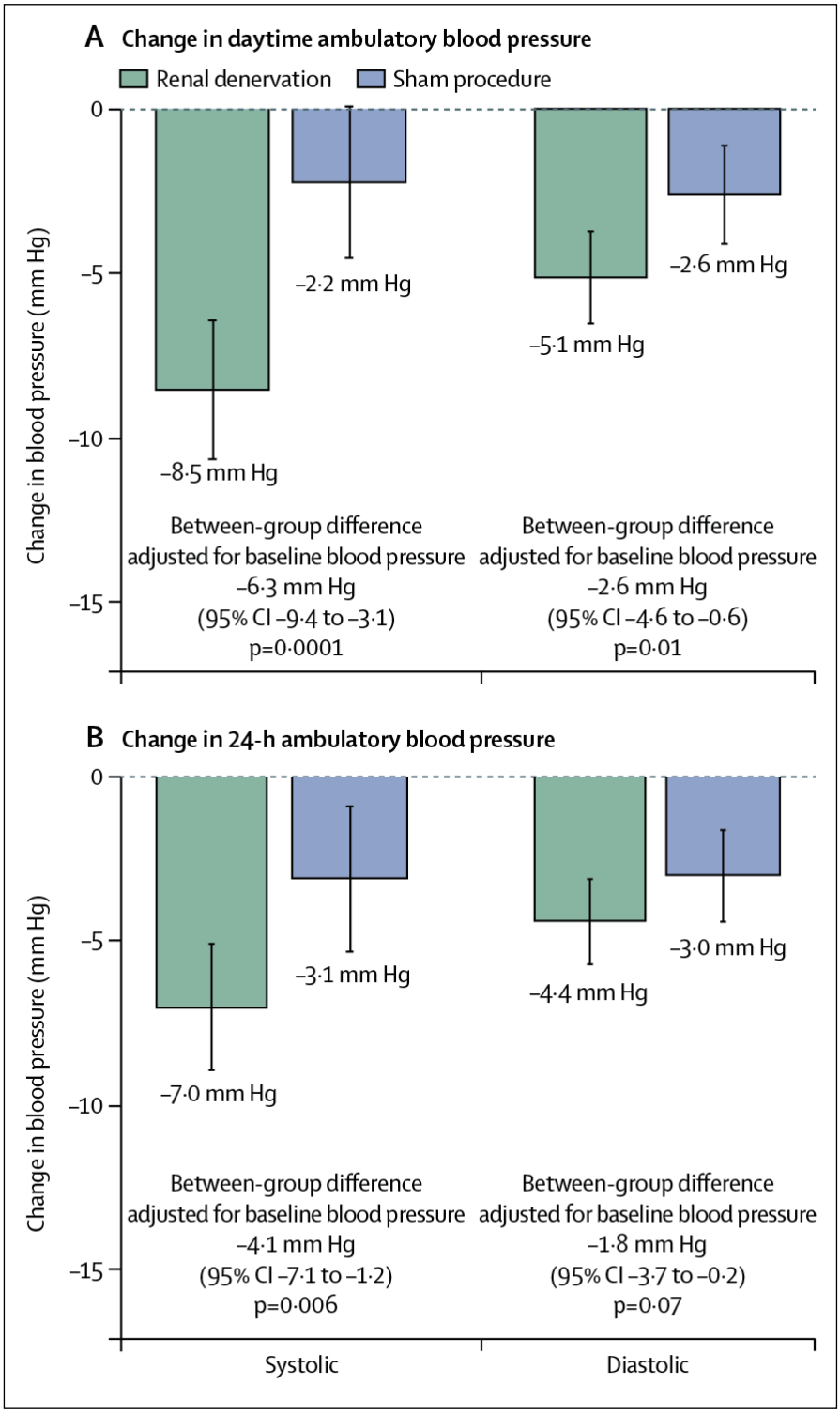


Figure 2: **Change in ambulatory blood pressure from baseline to 2 months in the intention-to-treat population.**
74 patients in the renal denervation group and 72 patients in the sham procedure group were included in the analysis of (A) daytime ambulatory systolic and diastolic blood pressure and (B) 24-h ambulatory systolic and diastolic blood pressure. Data are presented as mean and 95% CIs.

▲圖二 意向處理分析中兩組別間血壓變化

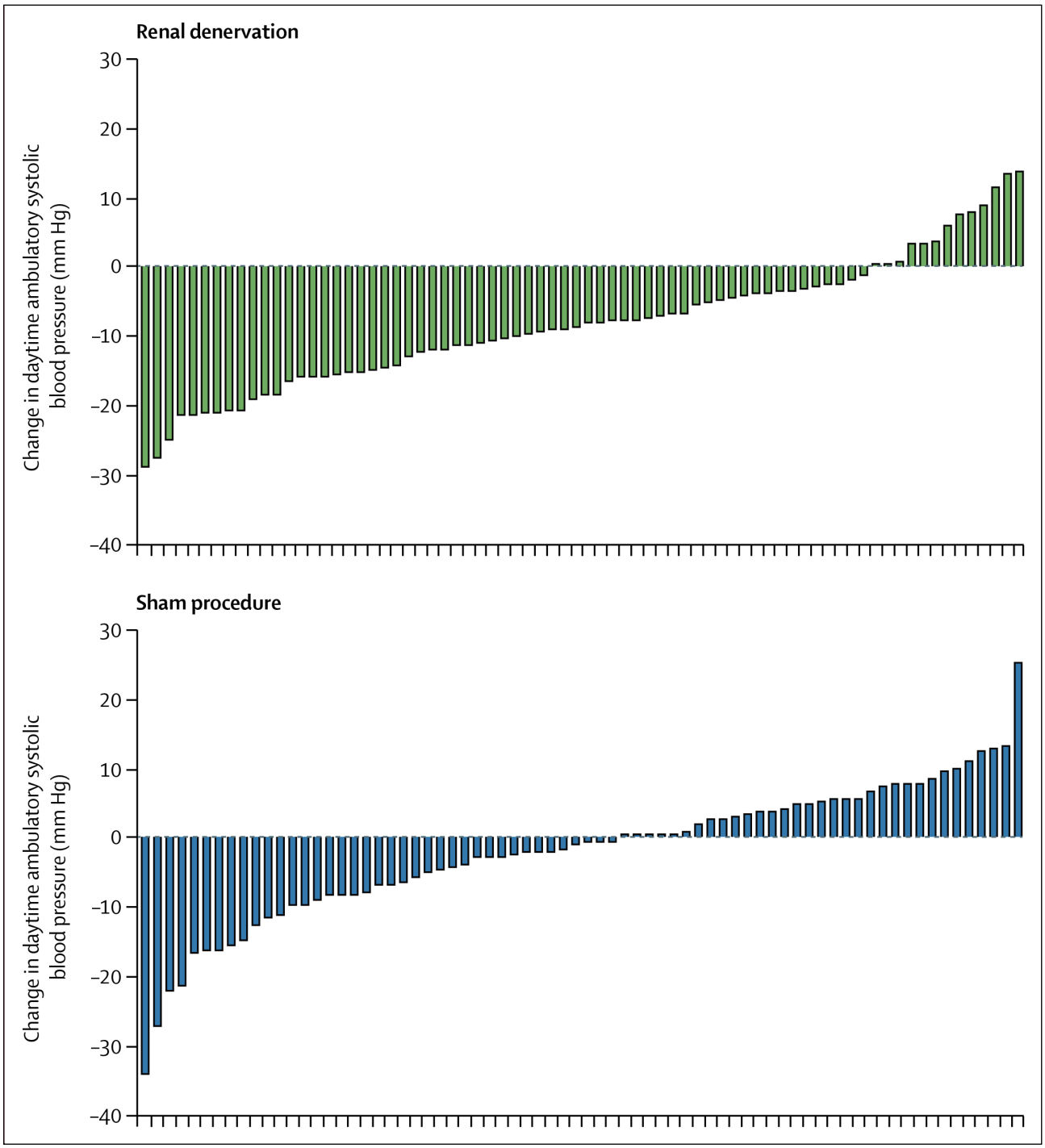


***Figure* 3: Individual patient changes in daytime ambulatory systolic blood pressure from baseline to 2 months**

Patients shown are those included in the intention-to-treat population.

▲圖三 個別患者兩個月內平日活動式血壓量測收縮壓變化

	Renal denervation	Sham procedure	p value
Intention-to-treat population			
Patients included in analysis	74	72	..
Daytime ambulatory blood pressure <135/85 mm Hg	17 (23%)	8 (11%)	0·06
24-h ambulatory blood pressure <130/80 mm Hg	20 (27%)	6 (8%)	0·003
Office blood pressure <140/90 mm Hg	19 (26%)	10 (14%)	0·07
Patients achieving controlled blood pressure in the absence of antihypertensive medication (intention-to-treat population*)			
Patients included in analysis	74	72	..
Daytime ambulatory blood pressure <135/85 mm Hg	15 (20%)	2 (3%)	0·001
24-h ambulatory blood pressure <130/80 mm Hg	18 (24%)	2 (3%)	0·0002
Office blood pressure <140/90 mm Hg	17 (23%)	5 (7%)	0·01
Per-protocol population			
Patients included in analysis	64	58	..
Daytime ambulatory blood pressure <135/85 mm Hg	14 (22%)	2 (3%)	0·003
24-h ambulatory blood pressure <130/80 mm Hg	16 (25%)	2 (3%)	0·0008
Office blood pressure <140/90 mm Hg	15 (23%)	5 (9%)	0·03

Data are n (%) unless otherwise noted. *Intention-to-treat population includes five patients in the renal denervation group and 13 patients in the sham group who restarted medications before the 2-month ambulatory blood pressure measurement evaluation.

Table 3: **Patients achieving controlled blood pressure by population and treatment group**

▲表三：兩組別血壓控制目標的達成率比較

Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries

Long-Term Results of the IN.PACT SFA Randomized Trial

Peter A. Schneider, et al.

Circ Cardiovasc Interv. 2018 Jan;11(1):e005891.

BACKGROUND

Randomized controlled trials have reported favorable 1-year outcomes with drug-coated balloons (DCBs) for the treatment of symptomatic peripheral arterial disease when compared with standard percutaneous transluminal angioplasty (PTA). Evidence remains limited on the durability of the treatment effect with DCBs in the longer term.

Methods and Results

IN.PACT SFA is a single-blind, randomized trial (Randomized Trial of IN.PACT Admiral Paclitaxel-Coated Percutaneous Transluminal Angioplasty [PTA] Balloon Catheter vs Standard PTA for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery [SFA] and/or Proximal Popliteal Artery [PPA]) that enrolled 331 patients with symptomatic (Rutherford 2–4) femoropopliteal lesions up to 18 cm in length. Patients were randomized 2:1 to receive treatment with DCB or PTA. The 36-month assessments included primary patency, freedom from clinically driven target lesion revascularization, major adverse events, and functional outcomes. At 36 months, primary patency remained significantly higher among patients treated with DCB compared with PTA (69.5% versus 45.1%; log rank P<0.001). The rates of clinically driven target lesion revascularization were 15.2% and 31.1% (P=0.002) for the DCB and PTA groups, respectively. Functional outcomes were similarly improved between treatment groups even though subjects in the DCB group required significantly fewer reinterventions versus those in the PTA group (P<0.001 for target lesion revascularization, P=0.001 for target vessel revascularization). There were no device- or procedure-related deaths as adjudicated by an independent Clinical Events Committee.

Conclusions

Three-year results demonstrate a durable and superior treatment effect among patients treated with DCB versus standard PTA, with significantly higher primary patency and lower clinically driven target lesion revascularization, resulting in similar functional improvements with reduced need for repeat interventions.

藥物釋放型球囊於股腘動脈持續三年治療效果 IN.PACT SFA 隨機分派試驗長期追蹤結果

編譯：臺大醫院 心臟內科 蕭文彬醫師

背景

藥物釋放型球囊 (Drug-coated balloons, DCB) 在過去隨機對照試驗，已證實相對於標準經皮動脈導管擴張術 (Percutaneous transluminal angioplasty, PTA)，在有症狀的周邊動脈疾病患者，有較好的一年預後。但目前藥物釋放型球囊長期持續性的治療預後仍缺發相關的證據。

方法與結果

IN.PACT SFA (Randomized Trial of IN.PACT Admiral Paclitaxel-Coated Percutaneous Transluminal Angioplasty [PTA] Balloon Catheter vs Standard PTA for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery [SFA] and/or Proximal Popliteal Artery [PPA]) 是一個單盲與隨機分派之臨床試驗，共納入 331 個位 Rutherford Classification 2 到 4 級，且股腘動脈病灶長度大於 18 公分的病人。以 2:1 的比例隨機分派至藥物釋放型球囊治療 (DCB) 與經皮動脈導管擴張術 (PTA)。治療後追蹤 36 個月，分析血管暢通度、免於目標病灶血管再通術 (Freedom from clinical driven target lesion revascularization)、功能方面預後 (Functional outcome) 與重大不良事件 (Major adverse events)。藥物釋放型球囊治療 (DCB) 在維持血管暢通 (69.5% vs. 45.1%; P<0.001) 與免於目標病兆血管再通術 (15.2% vs. 31.1%; P=0.002) 方面，明顯優於經皮動脈導管擴張術 (PTA)。而功能方面預後兩者無統計上差異，但 DCB 相對於有明顯較低的再治療的差異 (目標病灶再治療率，TLR P<0.001; 目標血管再治療率，TVR，P=0.001)。此外，本次試驗並無器材或治療導致的死亡個案。

結論

三年追蹤的結果顯示，DCB 相對於 PTA 有較高血管暢通度與較低目標病灶血管再通術比率。即使相近的功能預後，DCB 仍有較低的再治療率。整體而言對於 Rutherford Classification 2 到 4 級，且股腘動脈病灶長度大於 18 公分的病人，DCB 有較持續且較好的治療效果。

Table 1. Baseline Subject and Procedural Characteristics*

Characteristic	DCB (Subjects=220/ Lesions=221)	PTA (Subjects=111/ Lesions=113)	*P* Value
Age, y	67.5±9.5	68.0±9.2	0.612
Male	65.0 (143/220)	67.6 (75/111)	0.713
Diabetes mellitus	40.5 (89/220)	48.6 (54/111)	0.161
Hypertension	91.4 (201/220)	88.3 (98/111)	0.431
Hyperlipidemia	84.5 (186/220)	82.0 (91/111)	0.637
Current smoker	38.6 (85/220)	36.0 (40/111)	0.719
ABI/TBI†	0.769±0.228	0.744±0.189	0.308
Rutherford Clinical Category			0.898
2	37.7 (83/220)	37.8 (42/111)	
3	57.3 (126/220)	55.9 (62/111)	
4	5.0 (11/220)	5.4 (6/111)	
5	0.0 (0/220)	0.9 (1/111)‡	
Lesion length, cm	8.94±4.89	8.81±5.12	0.815
Total occlusions	25.8 (57/221)	19.5% (22/113)	0.222
Calcification	59.3 (131/221)	58.4 (66/113)	0.907
Severe calcification	8.1 (18/1221)	6.2 (7/113)	0.662
Dissections			0.360
0	36.2 (80/221)	38.9 (44/113)	
A–C	63.8 (141/221)	60.2 (68/113)	
D–F	0.0 (0/221)	0.9 (1/113)	
Provisional stenting	7.3 (16/220)	12.6 (14/111)	0.110

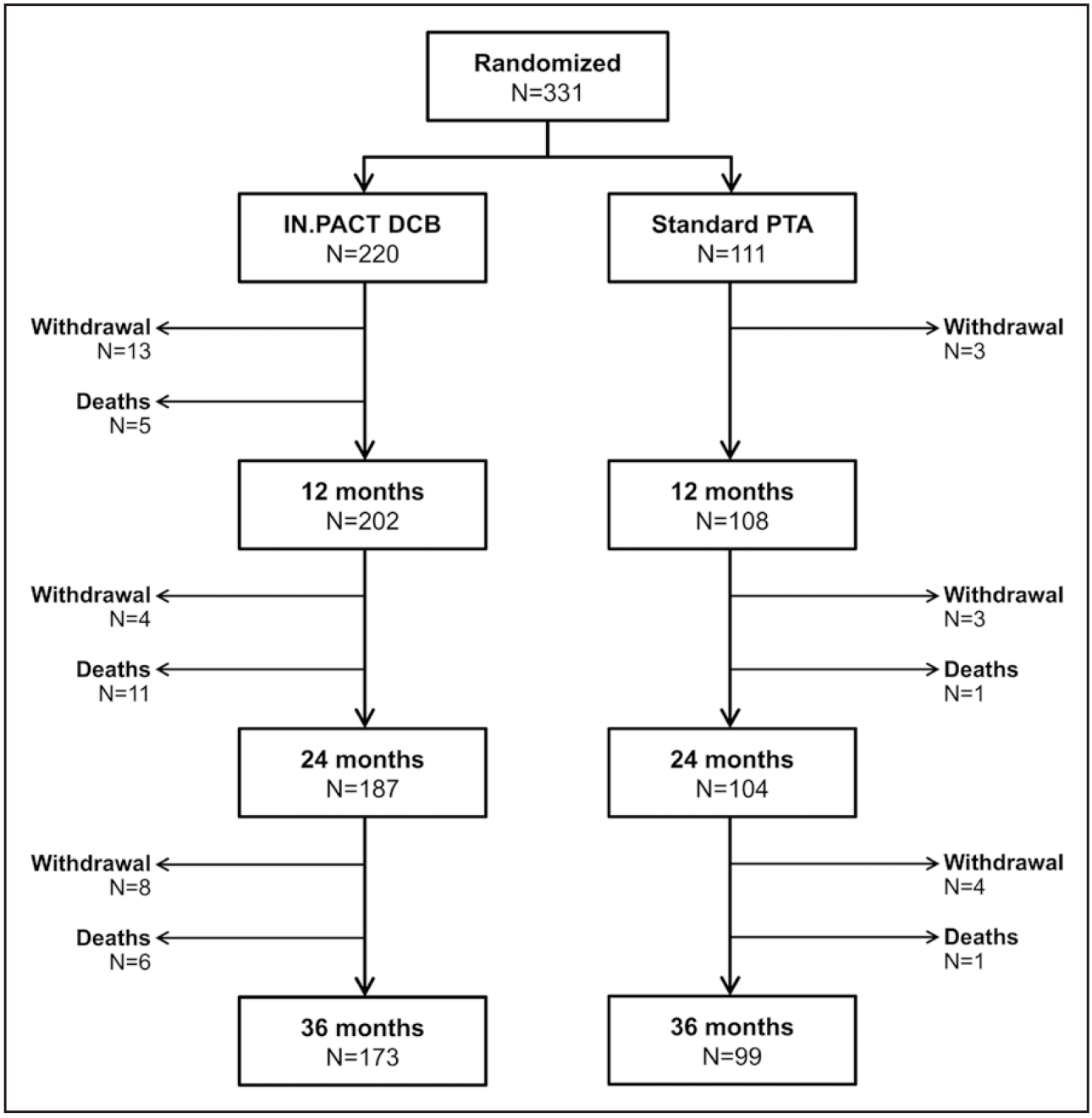
ABI indicates ankle-brachial index; DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty; and TBI, toe-brachial index.

*Values are mean±SD or % (n/N).

†TBI allowed in cases of incompressible vessels in IN.PACT SFA phase II.

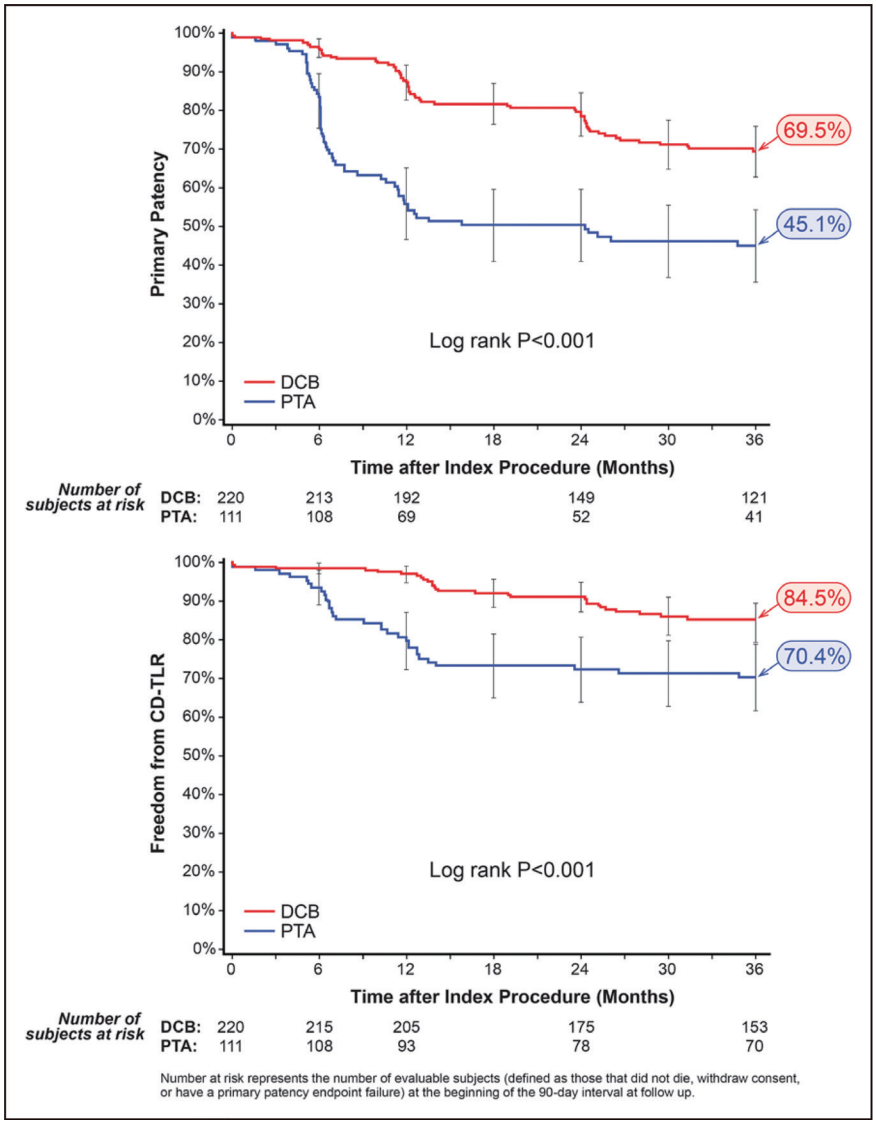
‡One subject in the PTA group was Rutherford Clinical Category 5 despite application of Rutherford Category 2 to 4 as inclusion criteria for enrollment.

▲表一



▲圖一

Figure 1. Subject flow in the IN.PACT SFA trial through 36 months. Three hundred thirty-one subjects were randomized 2:1 into groups that received percutaneous transluminal angioplasty (PTA) with a paclitaxel drug-coated balloon (DCB) or a standard uncoated balloon (PTA). Subjects are being followed for 5 years, and the results of intent-to-treat analyses have been previously reported for 12 months[18] and 24 months.[19]



▲圖二

Figure 2. Durability of effect after treatment with a paclitaxel drug-coated balloon (DCB) for femoropopliteal lesions: primary patency and freedom from clinically driven target lesion revascularization (CD-TLR) at 36 months. **Top**, Primary patency by Kaplan–Meier estimate was significantly higher in the DCB group compared with the percutaneous transluminal angioplasty (PTA) group (log-rank test, *P*<0.001). **Bottom**, Freedom from CD-TLR by Kaplan–Meier estimate was significantly higher in the DCB group compared with the PTA group (log-rank test, *P*<0.001). **Top**, **Bottom**, Bars represent 95% confidence intervals. The number of subjects at risk represents the number of evaluable subjects at the beginning of each 90-day interval. An independent and blinded Clinical Events Committee adjudicated all target lesion revascularization events, and independent and blinded core laboratories reviewed all ultrasound and angiographic images.

Table 2. Effectiveness Outcomes at 36 Months*

Characteristic	DCB (Subjects=220)	PTA (Subjects=111)	*P* Value†
Primary patency‡	69.5 (59)	45.1 (59)	<0.001§
CD-TLR‖	15.2 (30/197)	31.1 (32/103)	0.002
Time to first CD-TLR, d			
Mean±SD	542.9±278.2	302.9±213.0	<0.001¶
Median	464.0	243.5	
Interquartile range (Q3–Q1)	370.0	186.0	
Min, Max	1, 1080	1, 1045	
All TLR#	16.2 (32/197)	34.0 (35/103)	<0.001
Primary sustained clinical improvement**	68.7 (114/166)	52.6 (51/97)	0.012
ABI/TBI††	0.917±0.231	0.894±0.194	0.429

ABI indicates ankle-brachial index; CD-TLR, clinically driven target lesion revascularization; DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty; and TBI, toe-brachial index.

*Values are % (n), % (n/N), or mean±SD.

†Unless otherwise specified, all tests were for superiority using the Fisher exact test for binary variables and Student *t* test for continuous variables.

‡Defined as freedom from CD-TLR or freedom from restenosis as determined by duplex ultrasonography peak systolic velocity ratio ≤2.4 within 36 months. The 36-month primary patency was calculated based on Kaplan–Meier estimate, and the number of primary patency failure subjects is displayed in the parentheses.

§Log rank *P* value.

‖Defined as any reintervention at the target lesion because of symptoms or drop of ABI of ≥20% or >0.15 when compared with postprocedure baseline ABI/TBI.

¶Wilcoxon rank-sum test *P* value.

#Includes clinically-driven and incidental or duplex-driven TLR.

**Defined as freedom from target limb major amputation, target vessel revascularization, and increase in Rutherford class.

††TBI allowed in cases of incompressible vessels in IN.PACT SFA phase II.

▲表二

Table 3. Safety Outcomes at 36 Months*

Characteristic	DCB (Subjects=220)	PTA (Subjects=111)	*P* Value†
Primary composite safety‡	81.2 (160/197)	64.1 (66/103)	0.002
Major adverse events§	27.9 (55/197)	37.9 (39/103)	0.089
All-cause deaths‖	10.7 (21/197)	1.9 (2/103)	0.006
Device- or procedure-related deaths	0.0 (0/197)	0.0 (0/103)	N/A
Clinically driven TVR	18.8 (37/197)	35.9 (37/103)	0.002
Target limb major amputation	0.0 (0/197)	0.0 (0/103)	N/A
Thrombosis	2.0 (4/197)	4.9 (5/103)	0.283

DCB indicates drug-coated balloon; PTA, percutaneous transluminal angioplasty; and TVR, target vessel revascularization.

*Values are % (n/N).

†*P* values are based on Fisher exact test for superiority with significance level of 0.05.

‡Defined as 30-day freedom from device- and procedure-related death and target limb major amputation and 36-month freedom from clinically driven TVR.

§Composite of death, clinically driven TVR, target limb major amputation, and thrombosis.

‖No deaths were adjudicated as device- or procedure-related by the Clinical Events Committee. Median postindex days to death was 610 days (DCB) and 637 days (PTA).

▲表三

Table 4. Functional Outcomes at 36 Months*

	DCB		PTA		
Outcomes	Baseline	36 mo	Baseline	36 mo	*P* Value
6MWT†					
Mean distance, m					0.988‡
					0.583§
N	119	55	60	29	
Mean±SD	253.2±123.0	282.9±129.7	256.0±114.7	292.6±124.0	
Median [IQR]	274.3 [208.8]	289.6 [219.5]	278.6 [159.9]	304.8 [156.4]	
Change from baseline, m					0.117§
N	…	54	…	29	
Mean±SD	…	9.0±119.1	…	56.0±101.4	
Median [IQR]	…	25.1 [149.5]	…	61.0 [83.2]	
WIQ, %					
Walking impairment					0.799‡
					0.785§
N	214	158	109	91	
Mean±SD	42.1±28.9	71.8±34.2	41.3±29.9	74.7±29.2	
Median [IQR]	50.0 [25.0]	100.0 [50.0]	50.0 [25.0]	75.0 [50.0]	
Walking distance					0.861‡
					0.680§
N	177	95	83	46	
Mean±SD	32.3±27.7	67.4±37.8	30.4±24.2	65.0±37.9	
Median [IQR]	26.5 [41.2]	89.3 [65.5]	27.6 [36.2]	79.8 [72.4]	
Walking speed					0.847‡
					0.351§
N	177	96	82	46	
Mean±SD	31.8±23.5	52.4±31.6	29.3±17.1	47.1±28.4	
Median [IQR]	26.1 [29.3]	56.5 [51.1]	27.2 [26.1]	46.7 [38.0]	
Stair climbing					0.802‡
					0.786§
N	175	96	83	46	
Mean±SD	42.5±31.3	66.4±36.8	40.7±29.0	68.2±35.9	
Median [IQR]	41.7 [50.0]	75.0 [62.5]	37.5 [50.0]	83.3 [67.7]	

6MWT indicates 6-minute walk test; DCB, drug-coated balloon; IQR, interquartile range; PTA, percutaneous transluminal angioplasty; and WIQ, Walking Impairment Questionnaire.

*Values are mean±SD (n). The number of subjects evaluated at each interval is reported in parentheses. Based on number of subjects with available data. Site-reported data.

†Data collected in IN.PACT SFA phase II only.

‡Wilcoxon test for comparison of treatment groups at baseline.

§Wilcoxon test for comparison of treatment groups at 36 months.

▲表四


Boston Scientific
SYNERGY™
曹殿萍
盧澤民
羅秉漢
曾春典


殷偉賢
TSCI


蔡依霖


陳政瑋
TSCI


Meet the Masters

107.5.5 Meet the Masters


陳科維
潘恆宇
董穎璋
黃成偉
邱淳志
TSCI


Boston Scientific
Advancing science for life™
SYNERGY™
Everolimus-Eluting Platinum Chromium Coronary Stent System
HEAL
WITH CONFIDENCE

107.5.5 Meet the Masters

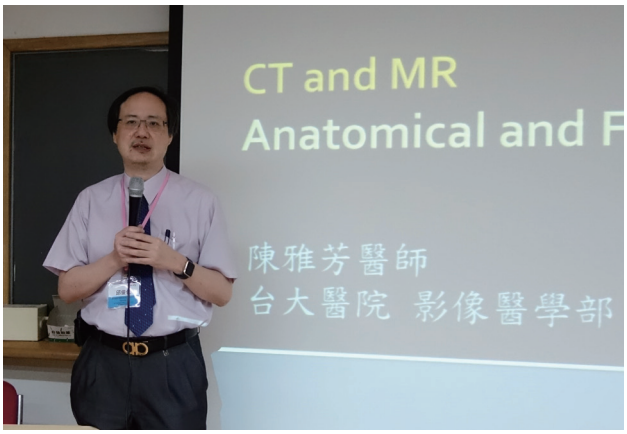

Meet the Masters
Thank you for your attention
SYNERGY
HEAL


SYNERGY
HEAL


Meet the Masters

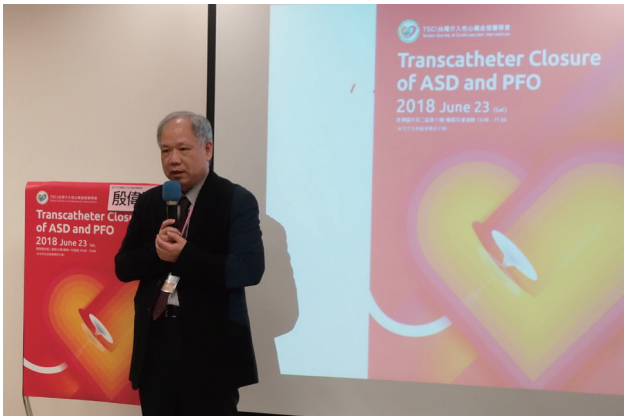

殷偉賢
TSCI

107.6.9 Carotid Stenting Training Course



107.6.9 Carotid Stenting Training Course

107.6.23 Transcatheter Closure of ASD and PFO

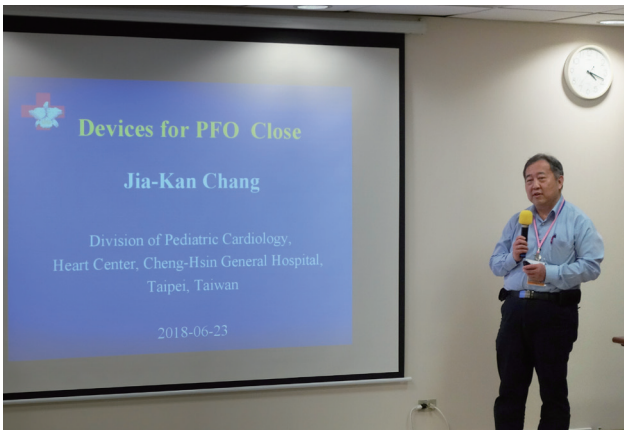



殷偉賢
黃碧桃


PFO and stroke


Transcatheter Closure of ASD and PFO
心房中膈缺損暨卵圓孔介入治療研討會
Special considerations for PFO closure
徐宗正 Tsung-Cheng Shyu
中國醫藥大學兒童醫院


2017.06.23 TSCI
Transcatheter Closure of ASD and PFO
Echocardiographic guidance of device closure for ASD and PFO
Chien-Fu Huang
殷偉賢


Devices for PFO Close
Jia-Kan Chang
Division of Pediatric Cardiology,
Heart Center, Cheng-Hsin General Hospital,
Taipei, Taiwan
2018-06-23

EuroPCR 2018
May 22-25 2018, Paris, France

台大醫院 高憲立 (H.L. Kao) 醫師：
- Case presentation: Orsiro in daily practice
- Case presentation: Orsiro in complex lesions
- Essential CTO techniques: explained and applied

台大醫院 蔡佳醍 (C.T. Tsai) 醫師：
- IVUS-guided parallel wire technique for double CTO lesions

振興醫院 尤和平 (H.P. Yu) 醫師：
- Transcatheter mitral valve-in-valve implantation for recurrent paravalvular leakage of mitral bioprosthetic valve

林口長庚 林佳濱 (C.P. Lin) 醫師：
- IVUS: the only weapon to success

林口長庚 劉冠良 (K.L. Liu) 醫師：
- Critical left main ostium disease complicated by catheter-related dissection

台北榮總 吳靜如 (C.J. Wu) 醫師：
- PCI for heavily calcified CTO of right coronary artery

台中榮總 林俊呈 (J.C. Lin) 醫師：
- Mini-debulk of CTO proximal cap by rotablation help to overcome CTO segment

台中榮總 鄧欣一 (H.I. Teng) 醫師：
- IVUS-guided true lumen re-entry for CTO PCI (side-branch marker technique)

高雄榮總 江承鴻 (C.H. Chiang) 醫師：
- Application of dual lumen catheter in management of coronary perforation

馬偕醫院 李俊偉 (C.W. Lee) 醫師：
- It's never too late!
- Nightmare comes without caution

馬偕醫院 林書毅 (S.I. Lin) 醫師：
- Real-time IVUS-guided CTO wiring via bilateral transradial approach

光田醫院 楊峯菁 (F.C. Yang) 醫師：
- The complete recovery of an elderly woman with severe dizziness

Other Faculties：

台大醫院 林茂欣 (M.S. Lin) 醫師
台北國泰 黃啟宏 (C.H Huang) 醫師
台北榮總 黃少嵩 (S.S. Huang) 醫師
台中榮總 賴志泓 (C.H. Lai) 醫師
台北榮總 黃偉杰 (W.C. Huang) 醫師
台北榮總 蔡泉財 (C.T. Tsai) 醫師
林口長庚 劉冠良 (K.L. Liu) 醫師
高雄榮總 黃偉春 (W.C. Huang) 醫師
新光醫院 程俊傑 (J.J. Cheng) 醫師
彰化基督教醫院 李政良 (C.L. Lee) 醫師
振興醫院 曹殿萍 (T.P. Tsao) 醫師
振興醫院 殷偉賢 (W.H. Yin) 醫師

APVIC 2018
June 29 – July 1 2018, New Delhi, India

林口長庚 陳俊吉 (C.C. Chen) 醫師：
- Long SFA CTO TASC D – How Do I Treat from Taiwan Experience

義大醫院 曾維功 (W.K. Tseng) 醫師：
- Vessel prepration before DCB or stent implantation

INFORMATION FOR AUTHORS

Scope

Journal of Taiwan Society of Cardiovascular Interventions **(J Taiwan Soc Cardiovasc Intervent)** is an official Journal of Taiwan Society of Cardiovascular Interventions. It is a peer reviewed journal and aims to publish highest quality material, both clinical and scientific, on all aspects of Cardiovascular Interventions. It is published on a basis of 6 months.

Article Categories

Reviews, Original Articles, Brief articles including images, Case Reports, Letters to the Editor, Editorial Comments. Please look into each category for specific requirements and manuscript preparation.

Manuscript Preparation: General Guidelines

Taiwan Society of Cardiovascular Interventions reserves copyright and renewal on all material published. Permission is required from the copyright holder if an author chooses to include in their submission to ***Journal of Taiwan Society of Cardiovascular*** Interventions any tables, illustrations or other images that have been previously published elsewhere. Copy of the letter of permission should be included with the manuscript at the time of submission.

Manuscripts should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (*N Engl J Med* 1997;336:309-15). Text should be double-spaced throughout. The Title page, Abstract, Body Text, Acknowledgments, References, Legends, Tables and Figures should appear in that order on separate sheets of paper. Define all abbreviations at first appearance, and avoid their use in the title and abstract. Use generic names of drugs.

Covering Letter

The main author should write a covering letter requesting the publication of the manuscript and assuring that the other authors have read the manuscript and agree to its submission. The editorial board reserves the right to confirm this in case it needs to.

Title Page

The title page should include a Title, full names and affiliations of all authors, and an address, telephone number, facsimile number and E-mail address for correspondence. Acknowledgment of grant support should be cited. A short Running Title (40 characters or less) should be provided.

Abstract

A concise description (not more than 250 words) of the Purpose, Methods, Results, and Conclusions is required. Give 3-6 key words for indexing.

Body Text

The text of Original Articles should be divided into Introduction, Materials and Methods, Results and Discussion sections. Other article types may use other formats as described in specefic guidelines against each category of manuscript below. Acknowledgments are typed at the end of the text before references.

References

References are cited numerically in the text and in superscript. They should be numbered consecutively in the order in which they appear. References should quote the last name followed by the initials of the author(s). For less than four authors provide all names; for more than four, list the first three authors' names followed by "et al.". List specific page numbers for all book references. Refer to Index Medicus for journal titles and abbreviations. Examples are provided below. Authors are responsible for the accuracy of the citation information that they submit.

Journals

1. Xu J, Cui G, Esmailian F, et al. Atrial extracellular matrix remodeling and the maintenance of atrial fibrillation. *Circulation* 2004;109:363-8.
2. Boos CJ, Lip GY. Targeting the renin-angiotensin-aldosterone system in atrial fibrillation: from pathophysiology to clinical trials. *J Hum Hypertens* 2005;19:855-9.

Books

1. Gotto AJ, Farmer JA. Risk factors for coronary artery disease. In: Braunwald E, Ed. *Heart Disease: A Textbook of Cardiovascular Medicine.* 3rd ed. Philadelphia: Saunders, 1988:1153-90.
2. Levinsky NG. Fluid and electrolytes. In: Thorn GW, Adams RD, Braunwald E, et al, Eds. *Harrison's Principles of Internal Medicine.* 8th ed. New York: McGraw-Hill, 1977:364-75.

Tables
All tables should be cited, by number, in the text. It should be typed double spaced, give a title to each table and describe all abreviations or any added relevant information as a footnote. Type each table on a separate page.

Figures & Illustrations
Number figures in the order in which they appear in the text. Figure legends should correspond to figure/illustration numbers and appear on a separate sheet of paper. Prepare your figures according to your mode of submission:
e-mail Submission: Figures should be submitted in high-resolution TIF format, or alternatively in GIF, JPEG/JPG, or EPS format. The figures should be placed in separate files, named only with the figure numbers (e.g. "Figure1.tif".)
Regular Mail: Photographs and drawings should be unmounted, glossy prints, 5"×7" in size. Three sets of each illustration must be submitted in a separate envelope. Label the back of each figure with the title of the article and an arrow indicating the top of the figure.

Manuscript Preparation: Specific Guidelines
Review Articles. These are scholarly, comprehensive reviews whose aims are to summarize and critically evaluate research in the field and to identify future implications. Unsolicited reviews may be submitted to the editor-in-chief and will be subject to approval by the editorial board. Instructions for Title page, Abstract, References, Tables and Illustrations/figures remains the same. The text can follow independent pattern as per the authors desire, subject to approval of the editorial board.
Original Articles. Clinical human studies and experimental studies will appear in this category. It should not exceed 6,000 words including references and figure legends. It should conform the general pattern of submission i.e., Title page, Abstract, Body Text, References, Tables and Illustrations/figures.
Brief Articles including images. These will present brief clinical, technical, or preliminary experimental results or cardiovascular intervention related images and should not exceed 3,000 words. It should conform the general pattern of submission i.e., Title page, Abstract (< 200 words), Body Text, References, Tables and Illustrations/figures.
Case Reports. Case reports should not exceed 2,000 words in total with not more than 6 authors. Abstract should be less than 150 words. In the body text, the Materials and Methods and Results sections should be replaced with a Case Report(s) section which should describe the patient's history, diagnosis, treatment, outcome, and any other pertinent information. All other sections should follow the general format. Only two figures/illustrations are permitted. The number of references should not exceed 15.
Letters to the Editor. The editors welcome all opinions and suggestions regarding the journal or articles appearing in the journals. A title for the letter should be provided at the top of the page. The writer's full name should be provided. The Letter should be no more than 250 words long and may include one table or figure and up to four references. The editorial board reserves the right to edit any letter received. Author should provide a covering letter, on his/her own letterhead, to the Editor-in-Chief stating why the Letter should be published. If it is concerning a particular article in ***Journal of Taiwan Society of Cardiovascular Intervention*** it should be within 6 months of that article's publication.
Editorial Comments. These will include invited articles or brief editorial comments representing opinions of local and foreign experts in cardiovascular medicine and research. They should be 1000-1500 words in length and not more than 20 references should be cited.

Submission of Manuscripts: e-mail submission is preferable
e-mail submission to tsci.med@msa.hinet.net
Please prepare text file or Microsoft Word file for your manuscript. Figures should be submitted in high-resolution TIF format, or alternatively in GIF, JPEG/JPG, or EPS format. The figures should be placed in separate files, named only with the figure numbers (e.g. "Figure1.tif".)
Regular Mail: Three copies any kind of Manuscripts including figures/illustrations should be submitted to:
Editorial Office, Taiwan Society of Cardiovascular Interventions,
16F-18, No.50, Sec. 1, Zhongxiao W. Rd., Taipei 10041, Taiwan, R.O.C.

Time Line
The first decision will be made within 6 weeks from receipt of the manuscript. Once a manuscript, if sent by regular mail has been accepted, it should be submitted on a compact disc as a text file or Microsoft Word file.

Author Reprints and Costs
Fifty reprints of each article will be furnished to authors free of charge. Additional reprints will be charged at a rate of US$20 per 50 copies. No charges will be instituted for articles less than seven printed pages. The cost of color reproductions will be borne by the author.

AUTUMN SCIENTIFIC MEETING • PERIPHERAL COURSE

2018 TSCI
秋季會 暨
週邊介入手術示範課程

09.15 — 16

高雄義大皇家酒店

高雄市大樹區學城路一段153號

TSCI 臺灣介入性心臟血管醫學會